Exhibit 22

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1
            UNITED STATES DISTRICT COURT
           SOUTHERN DISTRICT OF NEW YORK
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3
     IN RE: ACETAMINOPHEN - ) MDL No. 3043
     ASD-ADHD PRODUCTS
4
     LIABILITY LITIGATION
                               ) Case No.
                                ) 1:22-md-03043-DLC
5
     THIS DOCUMENT RELATES TO: )
                                ) JUDGE DENISE
6
     All Cases, 1:22-md-03043 ) COTE
7
              WEDNESDAY, AUGUST 2, 2023
8
    CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER
9
10
11
              Videotaped deposition of Robert
12
    Cabrera, Ph.D., held at the offices of Tracey
13
    Fox & Walters, 440 Louisiana Street, Suite
14
    1901, Houston, Texas, commencing at 8:55 a.m.
15
    Central, on the above date, before Carrie A.
16
    Campbell, Registered Diplomate Reporter,
17
    Certified Realtime Reporter, Illinois,
18
    California & Texas Certified Shorthand
19
    Reporter, Missouri, Kansas, Louisiana & New
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14 (818) 999-2232' Counsel for The Kroger Co.	electrophilic chemicals to SH(thiol)-group of proteins	
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HAIGHT BROWN & BONESTEEL LLP	oxidative stress during brain development leading to impairment	
BY: KATIE M. TRINH (VIA ZOOM) ktrinh@hbblaw.com	of learning and memory	
HAIGHT BROWN & BONESTEEL LLP BY: KATIE M. TRINH (VIA ZOOM) ktrinh@hbblaw.com 555 South Flower Street, 55th Floor Los Angeles, California 90071 (213) 542-8000	11 Rule 26 Rebuttal Expert Report of 11 Robert M. Cabrera, Ph.D.	. 1
Counsel for Unknown Party		
21	Acetaminopnen Hepatotoxicity Reveals the Importance of Riclogical Endounts in Genomic	
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22	Pharmacovigilance Risk Assessment Committee (PRAC) Minutes from the meeting on 30 August - 02 September 2016	
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¹ 15 Case study on the utility of 298	DIRECT EXAMINATION Page 12
1 15 Case study on the utility of 298 hepatic global gene expression profiling in the risk assessment of the carcinogen furan, Jackson,	² QUESTIONS BY MR. MURDICA:
of the carcinogen furan, Jackson, et al.	³ Q. Good morning.
4 16 Interval review charge questions 312	⁴ A. Good morning.
- February 2018, AOP Information	⁵ Q. Could you state your name for
17 TSI 1355: Acetaminophen and 331 Effects during Pregnancy, January 24, 2018.	6 the record.
24, 2018. 7 FDACDER000145 - FDACDER000301	7 MR. TRACEY: Jim? Jim, can you
	8 hear me?
8 18 Acetaminophen use in pregnancy: 364 Examining prevalence, timing and indication for use in a prospective birth cohort, 10 Bandoli, et al.	Hear me:
prospective birth cohort, 10 Bandoli et al	9 MR. MURDICA: Yes, sir.
11 19 Association of Prenatal 369	MIK. TRACET. Team. So before
Acetaminophen Exposure Measured in Meconium With Risk of	we get started, I tillik Redecca has
Attention-Deficit/Hyperactivity 13 Disorder Mediated by	Tour of five articles that when Robert
11 19 Association of Prenatal 369 Acetaminophen Exposure Measured in Meconium With Risk of Attention-Deficit/Hyperactivity Disorder Mediated by Frontoparietal Network Brain Connectivity, Baker, et al.	was preparing, he looked at his notes
	and found them, and they were not on
Acetaminophen and Risk of ADHD,	ins wich. She's going to give mose to
1 stroin, et al.	you.
17 (Exhibits attached to the deposition.)	There's also one article that
19 CERTIFICATE445	was published like from two days ago,
20 ACKNOWLEDGMENT OF DEPONENT447	and until we get our agreement on now
21 ERRATA	to supplement the articles that are
	continuing to come out, we thought we
22 LAWYER'S NOTES449	better fiand it to you tills morning.
24	So Redecta is going to give
25	that to you now before we start,
	those those articles.
VIDEOGRAPHER: We are now on	MS. KING: Okay. And I counted
the record. My name is Brian Bobbitt.	² seven.
³ I'm a videographer for Golkow	³ MR. TRACEY: Okay. Sorry.
⁴ Litigation Services.	4 MR. MURDICA: All right. Let's
Today's date is August 2, 2023,	5 try this again. Anything else before
and the time is 8:55 a.m. Central	6 we get started?
⁷ Time.	7 MR. TRACEY: No, no, no. Sorry
8 This video deposition is being	8 about that.
9 held in Houston, Texas, in the matter	9 MR. WATTS: Welcome to Houston,
of Acetaminophen, Tylenol, ASD/ADHD	Jim.
Products Liability Litigation for the	MR. MURDICA: Yeah. Yes, I'm
United States District Court, Southern	sure those couldn't have been
District of New York.	transmitted earlier than right now.
The deponent is Robert Cabrera.	Thank you.
Counsel will be noted on the	¹⁵ QUESTIONS BY MR. MURDICA:
stenographic record.	¹⁶ Q. Good morning.
Our court reporter may now	¹⁷ A. Good morning.
swear in the witness.	Q. Please state your name for the
19	¹⁹ record.
ROBERT CABRERA, Ph.D.,	A. Robert Matthew Cabrera.
21 of lawful age, having been first duly sworn	Q. Robert Matthew Cabrera, we've
22 to tell the truth, the whole truth and	²² never met before right now; is that correct?
23 nothing but the truth, deposes and says on	23 A. That's correct.
behalf of the Defendant Johnson & Johnson, as	Q. How do you refer to yourself?
25 follows:	25 A. Robert.
TOHOWS.	A. RUUCII.

Q. Okay. How would you like me to	Q. Okay. And your focus through
² refer to you during this deposition?	² your career thus far has primarily been
³ A. Okay.	³ neural tube defects and major congenital
Q. Dr. Cabrera, what are your	⁴ malformations, right?
⁵ qualifications as a doctor, sir?	⁵ A. I work primarily in neural
⁶ A. I have a doctorate in medical	6 development, which includes neural tube
⁷ sciences.	defects.
8 Q. Are you a medical doctor?	⁸ Q. Okay. Has your focus in neural
9 A. I'm a medical scientist, not a	development been neural tube defects?
¹⁰ medical doctor.	A. Predominantly, yes.
Q. Are I understand you're part	Q. And predominantly it's been in
12 of a lab.	12 identifying causes and finding protective
Do the other people in the lab	measures to prevent them; is that fair?
refer to each other as doctors when they're	A. We look at both the cause and
15 not medical doctors?	the prevention of birth defects, including
A. If you're in the lab, we refer	¹⁶ neural tube defects.
¹⁷ to each other as first names. If you're	Q. And in this litigation, you
outside of the lab, then we generally refer	submitted an expert report in June; is that
19 to each other by our titles.	¹⁹ right?
Q. Okay. And you understand	A. That's correct.
²¹ you're here in relation to a litigation,	Q. It was about 200 pages?
²² correct?	A. Approximately.
²³ A. Yes, I do.	Q. A week later you amended your
Q. And that's not your normal	²⁴ report, correct?
²⁵ work; it's not litigation, right?	A. That's correct.
¹ A. No. It's not my normal,	Q. Okay. Why did you amend your
² everyday job.	² report?
³ Q. Okay. Who employs you in your	³ A. There was some minor edits that
⁴ everyday job?	⁴ needed to be corrected that we had noticed.
⁵ A. Baylor College of Medicine.	⁵ Q. What do you mean "we had
⁶ Q. Does Baylor College of Medicine	6 noticed"?
⁷ know that you're here today?	A. Well, reading through the
8 A. I'm on vacation.	⁸ documents afterwards, it was there were
⁹ Q. Okay. Does Baylor College of	⁹ some things that were done that were left
¹⁰ Medicine know the opinions that you've put	incomplete and needed to be corrected.
¹¹ forth in this litigation with respect to the	Q. So were they things you added
¹² acetaminophen?	12 to or things you corrected?
A. I'm not submitting them on	A. Corrections, just corrections
¹⁴ behalf of Baylor.	that were made.
Q. Okay. So they have not taken a	Q. Did you remove anything?
position one way or another whether it's	A. Specifically, I don't I
¹⁷ appropriate for you to opine on acetaminophen	don't recall that we removed anything.
18 outside of work?	Q. You don't recall that you
¹⁹ A. I have not.	removed anything?
Q. Okay. Do they know you're	²⁰ A. No.
²¹ doing this work?	Q. Did you add anything?
²² A. They do not.	A. Edits. There was edits as far
²³ Q. Your training is primarily in	²³ as just edits.
²⁴ teratology; is that right?	Q. Typos or anything substantive
25 Δ That's correct	25 to your recollection?

A. That's correct.

25 to your recollection?

Page 18 ¹ the way it was presented. The hypothesis Not anything substantive, just ² would put forth that there was an ² typos, typographical errors. So between your original report all-or-nothing effect. ⁴ and your amended report a week later, there What has been shown is that ⁵ were no substantive changes? ⁵ early exposures, even before organogenesis ⁶ with specific teratogens, have been noted to I didn't make any substantive ⁷ be able to produce malformations and not changes, no. necessarily produce an all-or-nothing with Okay. At some point you those early exposures, and two of those provided a further supplemental report examples would be retinoic acid and alcohol. related to one article, correct? 11 11 Okay. And going beyond the That's correct. 12 ¹² 14 days, there are some structural defects And just now I was handed additional articles. that can be induced by teratogens, right? 14 14 Are those articles that you've A. Yes. 15 reviewed? And with time, we've come to 16 learn that some of them are induced at Yes, they are. A. 17 Okay. Are they articles that specific times, like cleft lip, for example. Q. you have additional opinions about? Is that fair? 19 They're consistent with my There is what's referred to as opinions that I've put forth in my report and critical windows of exposure that tend to define when particular organ systems are my supplemental. Q. Okay. Is there anything you susceptible to teratogenic effects of ²³ reviewed since your supplemental report ²³ teratogens. ²⁴ that's not consistent with your report that 24 And is one of those cleft lip? ²⁵ you haven't provided? Yes. There's a -- there's a Page 19 Page 21 1 time window as well for clefting or cleft A. No. ² lip. O. Okay. Do you have a draft of ³ an additional report in the works now or And would you say 21 to 28 days anything like that? is the key window for that? That would actually be a little I think -- I haven't started a bit early for cleft lip. new draft, no, not for the --So as of today, I have in Is that anything that you've writing whatever your opinions are, correct? ever studied, Doctor? I believe so, yes. Cleft lip? A. 10 Okay. I want to talk to you a Q. Q. Yes. ¹¹ little bit about teratology in early 11 A. Yes. pregnancy in particular. And specifically the In the first 14 days of teratologic window for cleft lip? ¹⁴ pregnancy, do you generally agree that any Yes. 15 teratologic event is an all-or-nothing event? Okay. How about for autism? A. Classically that was believed. What's the teratologic window for autism? ¹⁷ That is not necessarily the case, and that's So the neurodevelopment in the ¹⁸ been shown with -- particularly with alcohol human, it's continuous with neurulation, and retinoic acid. Those are exceptions. which is the start of neural tube closure and There's been so few mitoses in continues throughout gestation through both ²¹ the second and the third trimester of ²¹ the first few days of pregnancy that an ²² environmental effect or a teratological pregnancy. ²³ effect would most likely kill the embryo. 23 Yeah, okay. And I'm asking 24 Is that fair? specifically about autism. Classically, that's -- that's When is the teratologic

Page 22 ¹ effect that can -- I assume your testimony animal models and also consistent with ² here is that a teratologic effect can cause the studies of fever in humans. ³ autism in development, right? QUESTIONS BY MR. MURDICA: A. Yes. Q. A neural tube defect, which you Q. And when is the window for that ⁵ referred to earlier in the early part of ⁶ neurologic development, that would be much ⁶ teratologic effect for autism specifically, not neurodevelopment? more profound than autism, correct? Right. Well, it coincides Yes. It's a severe congenital ⁹ because autism is a neurodevelopmental malformation. It's often not compatible with ¹⁰ disorder. A teratogenic effect that occurs ¹¹ during its critical window of exposure, which 11 When you were first -- you're a ¹² includes development of the nervous system, member of the Teratologic Society, right? ¹³ and the development of the nervous system A. I -- what was referred to as ¹⁴ continues throughout gestation, both the ¹⁴ the Teratologic Society, which I still like second and third trimester. to think of as the Teratologic Society, I am still a member, yes. Okay. And so when would be the 17 ¹⁷ first window that a teratogen can affect the Q. You're still a member. 18 neuro -- neurological development? You're not a member -- are you So we've shown that -- in the familiar with OTIS? 20 ²⁰ animal model that it coincides with Α. I -- I am. ²¹ neurulation, so we can do exposures as early 21 O. You're not a member of that, ²² as eight and a half days of gestation which 22 are you? ²³ is the beginning of the neural tube closure, 23 A. I am not. ²⁴ which would coincide with approximately, as 24 Were you ever invited to be? ²⁵ you mentioned, 14 to 28 days in pregnancy. No, I haven't applied. Page 25 1 And during that critical window Okay. When did you first take Q. an interest in autism in particular, ² of exposure in the animal model, we're able ³ Dr. Cabrera, in your research? ³ to produce autism in animals that have been So for the last five years, ⁴ exposed during neurulation, so as early as ⁵ neurulation, but continues throughout ⁵ I've been working on another compound that ⁶ pregnancy. ⁶ was associated with neural tube defects, and ⁷ part of what we're doing is behavioral Okay. So is it fair that the O. ⁸ most critical -- to say that the most ⁸ testing. ⁹ critical window to induce autism in the So that's when I started to ¹⁰ opinion of Dr. Cabrera is 14 to 28 days of look at interactions and some overlap between ¹¹ the human pregnancy? early neural development and autism spectrum That is not my opinion, no. ¹² disorder, behaviors in animal models. A. 13 13 Okay. Please state for the And you're doing that at Q. ¹⁴ record Dr. Cabrera's opinion as to the most ¹⁴ Baylor? 15 important time for a tera -- teratogenic A. Yes. 16 inductions of autism in human pregnancy. O. And what's the compound? 17 17 A. Dolutegravir. It's an HIV So --18 MR. TRACEY: Objection. Form. antiviral. 19 19 THE WITNESS: So throughout O. And is that funded by any 20 neurulation and neural development, particular company? 21 that is the critical window of It's funded by the National 22 ²² Institutes of Health, the National Institutes exposure. I think the time of most 23 ²³ of Mental Health. sensitivity would be during the second 24 24 trimester of pregnancy. Whose drug is that, if

And that's been supported by

25

²⁵ anybody's, or is it an old drug?

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Page 26
                                                                                                            Page 28
             No. No. It's -- I can
                                                           <sup>1</sup> the hippocampus that are either signs or
 <sup>2</sup> double-check on that, but maybe Gilead.
                                                           <sup>2</sup> causal for autism?
             Okay. I want to talk to you a
                                                                       There have been documented some
 <sup>4</sup> little bit about the human brain for a
                                                           <sup>4</sup> structural changes. Actually, one of the
                                                             papers we gave you today shows some
 <sup>5</sup> minute.
                                                             structural changes in the hippocampus that
            Where in the human brain are
                                                           <sup>7</sup> were associated with acetaminophen exposures,
   the features that result in autism?
              So different parts of the brain
                                                             particularly in the autism model.
 <sup>9</sup> have been associated with autism. I don't
                                                                 Q. Yeah. And my questions were
<sup>10</sup> know that there's any one portion of the
                                                             about human beings, and I think what you're
<sup>11</sup> brain that specifically causes autism as a
                                                             referring to is a study in mice, correct?
<sup>12</sup> neurobehavioral disorder.
                                                          12
                                                                       That is correct.
                                                          13
       Q. So, in other words, whatever --
                                                                       Out of Wuhan, China?
                                                                 O.
<sup>14</sup> well, do you believe that there are
                                                          14
                                                                       Yes.
                                                                 Α.
                                                          15
<sup>15</sup> structural abnormalities in the brain of
                                                                 Q.
                                                                       Are you familiar with the lab
<sup>16</sup> patients with autism?
                                                          16
                                                             there?
                                                          17
17
              Those have been documented
                                                                       I'm -- not particularly.
                                                                 Α.
<sup>18</sup> in -- and, you know, one example is there was
                                                                       How important is your reliance
<sup>19</sup> a publication in the New England Journal of
                                                             on a mouse hippocampus study from Wuhan,
<sup>20</sup> Medicine by Stoner that demonstrated what
                                                          <sup>20</sup> China?
                                                          21
<sup>21</sup> I -- what I refer to as neural layering
                                                                       It's part of the totality of
<sup>22</sup> defects, and those are predominantly in the
                                                             evidence. I've considered it.
<sup>23</sup> frontal and occipital cortex.
                                                                       Okay. But you had the opinions
                                                          <sup>24</sup> you're going to talk to us today before
             But your testimony here today
<sup>25</sup> is that the structural manifestations of
                                                             seeing that study, right?
                                                 Page 27
                                                                                                           Page 29
                                                           1
 <sup>1</sup> autism can be in any portion, any anatomic
                                                                  A.
                                                                        Yes.
 <sup>2</sup> portion, of the human brain?
                                                                  Q.
                                                                        At what point did you come to
             Well, not any anatomic portion.
                                                             the conclusion that acetaminophen --
 <sup>4</sup> It would be predominantly those involved in
                                                             acetaminophen causes autism -- well, we'll --
 <sup>5</sup> executive function, reasoning, although some
                                                           <sup>5</sup> do -- we'll take it one at a time.
 <sup>6</sup> other ones have demonstrated that there's
                                                                       At what point in time did you
                                                             come to that opinion?
 <sup>7</sup> also some cerebellar involvement in some
 <sup>8</sup> patients with autism.
                                                                        So while I was reviewing the
                                                           <sup>9</sup> literature systematically, I realized that
             So what -- tell us the anatomic
                                                             there was a -- had accumulated an
   regions of the brain where there would be
<sup>11</sup> structural changes that are a part of autism
                                                          <sup>11</sup> overwhelming amount of evidence that
<sup>12</sup> or indicative of autism?
                                                             supported that position.
                                                          13
             So what's been documented
                                                                 Q.
                                                                        Okay. And was that in 2023?
                                                          14
<sup>14</sup> includes impacts on the neural laminal
                                                                        Yes, that's this year.
                                                                  A.
15 layers, which -- largely different areas of
                                                                        Okay. And were you
<sup>16</sup> the cerebral cortex and then also the
                                                             doing that -- were you systematically
<sup>17</sup> cerebellum.
                                                             reviewing the literature for fun or for some
18
                                                          18
                                                             other reason?
             Okay. How about the
                                                          19
19
   hippocampus?
                                                                  A.
                                                                        Because I was asked to.
                                                          20
              There is some data to support
                                                                        Okay. You were asked to, not
                                                                  O.
<sup>21</sup> interaction with the hippocampus as well.
                                                             for your job, right?
                                                          22
       Q. Okay. And I -- you used the
                                                                 A.
                                                                        For the -- for why I'm here
<sup>23</sup> word "interaction." I didn't ask about
                                                          23 today --
                                                          24
   interaction.
                                                                  Q.
                                                                        Yeah.
```

25

Are there structural changes in

-- as a consultant.

Page 30 And I'm going to ask you the primary instructor, is certified in genetics. ² So I'm a lecturer in that class. ² same question for ADHD. At what point in time did you Oh, I see. ⁴ come to the conclusion that acetaminophen So the class, if we looked at a ⁵ causes ADHD in human beings? syllabus -- or the class is actually taught It's concurrently. by your boss? In other words, concurrently in So, well, my boss's colleague. Q. 8 2023? 8 Q. Correct? Okay. Now I'm just confused. A. Yes. If we went and looked at the Had you ever looked at ¹¹ literature on acetaminophen and autism prior program for the school, does it say Dr. Cabrera is the professor? to 2023? 13 13 Α. I looked at literature on As a lecturer. A. 14 ¹⁴ acetaminophen generally, and I had also been Q. Okay. So much like I go to ¹⁵ following it sometime during COVID, but Baylor as a guest lecturer in a law class, ¹⁶ not -- hadn't conducted a systematic review. that doesn't make me a professor, correct? 17 17 O. Right. No, not unless you're appointed A. 18 And hadn't conducted a review a professor. ¹⁹ with respect to autism or ADHD in particular, Okay. Are you appointed a Q. ²⁰ correct? professor? 21 A. Incorrect. I had been Associate professor. A. 22 ²² reviewing studies, particularly the In -- at Baylor or at UT or Q. ²³ meta-analysis that had been published in the where? 24 ²⁴ last several years for my own class. A. At Baylor. 25 O. And what class is that? The Okay. Where do you teach your O. Page 31 nutrition class? nutrition class? No. I also teach two other So I'm not currently teaching ³ my nutrition class. I was teaching it at San ³ classes. One of them is medical Jacinto College and also UT in Austin. ⁴ biochemistry, in addition to a genetic ⁵ counseling class, and it was for the genetic And your nutrition class, was ⁶ counseling class. ⁶ that more in the vein of maternal nutrition Q. Okay. And what degrees or to prevent neural tube defects? ⁸ board certifications do you have in genetics? It's, let's say, a core class. ⁹ So we were required to teach a class as part A. I'm not a -- my boss is a ¹⁰ board-certified geneticist. I'm not a of our faculty appointment, and I was ¹¹ teaching a core credit class in nutrition. ¹¹ board-certified geneticist. ¹² So it was a general science class. And why are you talking about 13 your boss? Q. Was that the first class you ¹⁴ were -- you ever regularly taught? 14 Well, the class, I was referred 15 to as being able to teach this class. And so 15 No, it was not. 16 ¹⁶ that was who referred me as a -- said that I Okay. What was the first class Q. ¹⁷ could teach the class. you ever taught? 18 Does your boss teach the class, I -- before that, I was 19 or do you teach the class? teaching a class in the philosophy of science 20 as well. I teach the class. Okay. So you teach a class And does the philosophy of ²² about genetics and are not certified in ²² science have anything to do with autism or ²³ genetics in any way, correct? ²³ ADHD? 24 Well, the person -- again, my It did not, no.

25

O.

²⁵ boss, and then also the person that is the

Okay. And you said you teach a

Page 34 ¹ biochemistry class right now? ¹ medication and so we looked at that as well. And so while we were doing That's correct. A. 3 And what degrees do you have in ³ behavioral studies on those animals, we also chemistry or biology or biochemistry? ⁴ looked at the effect of in utero exposure on I trained in biology. ⁵ the behavior of offspring, and that was where ⁶ That's my -- my undergrad was in biology. ⁶ we started to look at autism. Okay. And that was a -- you Okay. said that was a follow-up grant, right? And the class that I teach, I A. teach genetics in that class. That's -- I That was -- yeah, that was a 10 cover the genetics lecture in that class. So follow-up. 11 ¹¹ I'm the lecturer in that class. Q. When did you get that follow-up 12 12 And is the audience medical grant? 13 13 students? A. About three years ago. 14 14 There's two different Q. Okay. So is it really three ¹⁵ audiences. One is graduate students. We years then you've been looking at autism? ¹⁶ have a graduate student section, and then I Well, that's when we got the ¹⁷ also teach a professional student section, grant to look at that, yes. ¹⁸ which is physician's assistants and 18 Q. And then you began after that, ¹⁹ orthopedic and nurse anesthesiologists. So 19 correct? 20 ²⁰ not medical students, professional students. Right. Right. A. Okay. I asked you a couple Okay. So it's not five years. ²² minutes ago about when you first became ²² You weren't studying autism five years ago, ²³ interested in autism, and I think you said correct? ²⁴ you've been working on a compound for the Initially we were studying ²⁵ neurodevelopment, and then that led into us ²⁵ last five years in relation to that. How does the compound that studying autism. ² you're doing -- how does your research relate Okay. And it wasn't ³ to autism? Is it whether the drug induces specifically autism that you were studying. 4 autism? Even in the last three years, it was ⁵ neurological effects of that compound, A. So initially there was a report ⁶ that there was neural tube defects in correct? ⁷ Botswana that happened just over five years A. That is correct. ⁸ ago, approximately five years, and we Q. That includes more than autism, ⁹ followed up that study with producing an right? 10 ¹⁰ animal model of that that would show that it A. Yes. 11 ¹¹ was fully responsive. And we've followed Q. What else does it include? 12 that up with now a mouse model that's also Well, in human patients, it's ¹³ shown that it's fully responsive just to show predominantly what's referred to as adverse events. And so adverse events reported ¹⁴ that this drug can produce neural tube defects that are fully responsive. included things like headache in patients, 16 Okay. And I asked you about potentially, and other, I guess, complaints O. ¹⁷ autism. that were neurological in people that were 18 A. Right. taking the medication. 19 19 Autism is not neural tube And has this research been O. ²⁰ defects, correct? published? 21 And then the -- on the The neural tube defects paper ²² follow-up for that, we were also funded to was just published, I believe, a couple weeks ²³ look at the neurological impacts because ²³ ago.

24

25

Q.

Uh-huh.

²⁴ these are also associated with neurological

²⁵ problems in people -- both adults taking the

Page: 10 (34 - 37)

And the behavioral studies we

Page 38 ¹ might change your conclusion? Is that what ¹ haven't published yet. Are you intending to? ² you're saying? Q. 3 A. Yes, we do. Yes. Okay. What, if any, Q. Okay. So if we went and looked O. ⁵ conclusions did you come to as to what you're ⁵ at the grant that you got that you're talking ⁶ about for this compound, would it say that calling behavioral effects of that compound? you were investigating autism? So we've seen increased activity in those animals that we documented It does not. Α. in open field testing. O. Okay. Would it say that you're investigating ADHD? And what does that increased 11 11 activity mean to you? It would not. 12 12 Well, there's different Okay. So is this work that 13 interpretations, but potentially anxiety in you're doing here, this is the first time you ¹⁴ actually examined specifically autism and ¹⁴ the animals. ADHD in relation to any particular Okay. And does the anxiety ¹⁶ allow you to opine that that compound causes environmental exposure. 17 any particular neurologic effect or defect? Is that fair? 18 Yeah. So we follow that up A. That is not correct. with looking at the brain and doing brain Okay. What else have you -pathology, and also metabolomics on the brain what other work have you done evaluating as well. autism and ADHD as an outcome to an exposure? 22 O. Okay. So you sacrifice the When I was in graduate school, animal and examine the mouse brain? ²³ we also did a behavioral study looking at the 24 ²⁴ exposure of valproic acid and heavy metals in Yes. 25 ²⁵ autism core behaviors. Okay. And what conclusions, if Page 41 ¹ any, did you draw between that compound and Okay. And that -- was that in ² a particular lab in grad school? ² causation as to any particular neurologic ³ effect? A. Yes, it was. 4 And is it the same lab you work A. Suffice it to say, we do see O. ⁵ changes in single carb metabolism that ⁵ in now? ⁶ appears to be affecting dopaminergic Well, we've come a long ways, ⁷ pathways, but we haven't drawn any but, yes, I still work for the same person. ⁸ conclusions other than the fact that there --Q. Okay. So in grad school, was ⁹ the animal has increased anxiety at this that Richard Finnell's lab? 10 point. Yeah, he was the director of 11 ¹¹ the institute and also the PI of the lab. Q. Okay. So increased anxiety in ¹² a mouse model doesn't necessarily mean that 12 Q. And he was looking at Depakote, it causes any particular neurologic defect? or valproic acid, and neurologic outcomes? Not exactly. A colleague of It can be consistent with other mine, Denise Hill, was interested in heavy ¹⁵ problems, but we haven't seen other problems ¹⁶ in the animal. That was one of the things metal toxicity, and we appreciated that ¹⁷ that we noted that was statistically ¹⁷ valproic acid was the model for autism in animal models, particularly in mice. And so significant in the study that we did. 19 And what other problems would we compared heavy metal exposure with ²⁰ valproic acid in those animal models. 20 you look for? So some of the things that can To what endpoint? To see if ²² be looked for is we also do three-chamber for the heavy metal exposure could induce autism? ²³ socialization. We didn't see changes in 23 Autism-like behaviors, yes. 24 socialization in that animal. Okay. And was that published? Q. 25 Okay. And if you had, then it Yes, it was.

Page 42 Page 44 ¹ treatments, like valproic acid and Q. Okay. And had you ever done ² neural tube defect research on valproic acid ² phenobarbital, those are known teratogens, ³ before that? correct? A. A. Yes. Particularly valproic acid ⁵ is -- they're potent teratogens. Q. Was that also in your grad By the time you were in grad school research? ⁷ school, everybody agreed and knew that A. Yes, it was. ⁸ first-line AEDs could induce major congenital Okay. So your role, when you Q. ⁹ were in grad school, I take it, you weren't a malformations in human beings, correct? ¹⁰ lead investigator or anything like that on I would like to think that 11 that study? ¹¹ everyone knew, but there were still people 12 ¹² defending the position that they didn't. I In graduate school, I was --¹³ still argue incorrectly, but it was generally ¹³ well, one of those studies I was first author ¹⁴ understood that they were -- caused birth ¹⁴ but not the PI of the study. Okay. How about the autism and defects. ¹⁶ valproic acid study, were you first author 16 Q. Well -- and that's one of the ¹⁷ there? ¹⁷ reasons that you used it in the mouse model, 18 I was -- Denise was the -- that correct? 19 was her first author publication. I A. That's correct. 20 ²⁰ followed, second author. O. All right. And one of the 21 reasons that you knew that is because there And on that publication, if we had been prospective, double-blind pregnancy ²² looked at it, was that in an animal model, or ²³ were you making determinations as to human registries that showed a profound effect of ²⁴ effects? valproic acid on human pregnancy, correct? 25 A. Well, there had been initially That was in an animal model. Page 43 Page 45 1 retrospective studies that had identified Okay. So let me try again ² then. ² there was an effect of valproic acid, and then those were followed up by both animal Is this the first time you've models that demonstrated that, in addition to ⁴ ever opined that a compound -- an exposure prospective studies in women with epilepsy ⁵ can cause -- can induce autism in a human ⁶ being? treated and untreated. Okay. Are you familiar with A. Yes, it is. Okay. And you've never done the North American Antiepileptic Drug Q. ⁹ that or made that conclusion outside of Registry? ¹⁰ litigation ever before today in this year, 10 A. I am. 11 11 correct? Do you know Lew Holmes? Q. 12 12 Yeah, this is my first time I do. 13 13 offering an opinion on autism. Q. Sonia Hernandez-Diaz? 14 14 I've met her a couple of times. O. Okay. 15 15 Okay. So you know -- you know Or ADHD. Α. 16 16 how they conducted that registry, right? Back to valproic acid. 17 Valproic acid has been known to 17 Not at its inception, but I'm 18 18 familiar with the work. be a human teratogen for decades, correct? 19 19 A. That is correct. You're familiar that it's a It was one of the early human exposure registry? O. 21 antiepileptic drugs, the first -- first-line A. Ongoing. antiepileptic drug a long time ago, correct? 22 Q. Ongoing. 23 Discovered by chance, it was 23 In human pregnancies, right? 24 shown to be an effective antiepileptic drug. That's correct. A. 25 And those first-line O. With exposure to anti- --

Page 46 Page 48 ¹ unknown, blinded antiepileptic drugs, animal evidence is what matters? ² correct? Well, I disagree because I talk to physicians regularly that counsel women A. A variety of them now, yes. Q. And it's prospective. They're ⁴ that take anticonvulsant drugs, and they ⁵ quite often ask me what I see in the animal ⁵ followed -- they're enrolled right at the ⁶ beginning of pregnancy, right? ⁶ models to help inform them on the relative ⁷ risk of medications that they use that don't That's correct. have enough data on them. Q. Okay. And the Holmes and ⁹ Hernandez-Diaz are blind to the patient and Are you talking about the the drugs, right? third-line antiepileptics? 11 11 Well, looking at particularly That is my understanding until ¹² the analysis is done. the newer ones, yes. 13 Q. And it's double-blind, right? Well, you know -- you know 14 I -- I'm not sure about the ¹⁴ there isn't registry data on those yet, ¹⁵ double-blinding. I'd have to check that right, because they haven't reached particular publication you're referring to. significance? 17 Okay. Well, there's many 17 Well, yes, because there's not publications, right? enough exposures in the database yet. 19 Right. Right. A. Yes. 20 20 So I don't think we're Q. The pregnancy registry, they constantly publish any time something becomes understanding each other because I'm asking significant, right? you about drugs when we have human data, and 23 ²³ we do have a publication because it did A. They publish updates regularly. 24 ²⁴ become significant in the registry. Right. 25 And that level of evidence Okay? Page 49 Page 47 ¹ is -- would you agree it's about as good as For those drugs, not the newer ² you get in human pregnancy? ² ones, for those drugs, nobody is talking The combination of having an ³ about the animal data. They're talking about ⁴ animal model, having first observed this ⁴ the actual human data that became significant ⁵ prospectively -- or excuse me, ⁵ in a prospective, double-blind pregnancy ⁶ retrospectively and then doing the ⁶ registry, correct? ⁷ prospective study, that's -- that is strong A. That's largely what you will ⁸ evidence. ⁸ hear about as far as -- for clinical Okay. Well, I didn't ask you analysis. about the animal model. 10 Q. That's the highest level of 11 ¹¹ evidence you can get in human pregnancy A. Yeah. within the bounds of current ethics, correct? What matters to people now, we ¹³ have double-blind, prospective pregnancy Well, in addition to that, that ¹⁴ registry human evidence now today, correct? ¹⁴ can be distilled further into meta-analysis. That is -- we do. That would be the best set of data. 16 16 And if you ask anybody in the If there's multiple studies. Q. ¹⁷ field what the best evidence is, they're not 17 A. If there's multiple studies. going to start talking about animal studies. Okay. All right. And valproic ¹⁹ They're going to talk about the acid has had a major congenital malformation ²⁰ North American Antiepileptic Drug Pregnancy warning on the label, as the drug Depakote, ²¹ Registry and the publications that came out for decades, correct? 22 ²² of that, correct? As far as I know, yes. 23 23 Okay. And then eventually, A. I disagree. Okay. You disagree because you ²⁴ after it was already, essentially, not used

think now that we have human evidence, the

Page: 13 (46 - 49)

²⁵ in pregnancy unless no other AED would work.

Page 50 Page 52 ¹ an autism warning was added to it, correct? You don't know if FDA uses That is correct. AOPs, do you? O. Okay. Throughout your reports I'm not familiar with them A. ⁴ you mentioned many times an adverse outcome using AOPs. ⁵ pathway. Q. You've never seen them using an (Witness nods head.) AOP, correct? A. Like I said, I'm not familiar In particular, an AOP 20. Do ⁸ you remember including that in all of your with their use --9 reports --Q. By --10 10 A. Yes, I do. -- by the FDA. 11 11 Q. -- or at least your original Q. By the way, have you ever been 12 report, your amended report and your contacted by the FDA for assistance with 13 supplemental -- your rebuttal report all have regard to any particular compound? ¹⁴ AOP 20, correct? 14 A. Yes, I have. 15 15 A. That is correct. Okay. And is it the one that you were -- that you were talking about Q. Okay. And what organization ¹⁷ came up with that pathway? earlier that you're working on now? A. Well, that was published by the Well, with the entire class of ¹⁹ OECD, is -- it's where I found that molecules, the HIV integrase inhibitors, I was asked to go with the -- with the FDA, ²⁰ originally. Q. Okay. And what is the basis with the World Health Organization at the ²² National Institutes of Health and National ²² behind OECD? How do you know about them, and ²³ how do you use them in your regular work? ²³ Institutes of Child Health and Development ²⁴ and present the work I had done on that A. So the AOPs themselves I'm ²⁵ familiar with because I've done some work ²⁵ compound. Page 53 ¹ with the EPA in the past, and it's common for Q. Okay. And that was a -- some ² us to put AOPs together; to look for the ² sort of meeting? ³ existing evidence on a particular molecular A. It was a meeting, yes, a ⁴ interaction and whether it can have an impact ⁴ conference. ⁵ on an organism; and how it has an impact on O. And when was that? ⁶ the organisms and whether there's any gaps in I believe it's approximately ⁷ the data on having that impact on an six years ago now. I think I have it on my ⁸ organism. résumé for a conference I attended. Okay. And the AOP 20 that you Okay. So that was the neural ¹⁰ refer to a lot, you didn't publish that or tube defect work that was funded by the ¹¹ put that together, correct? ¹¹ National Institutes of Health? A. I did not. That was A. It ultimately led to the ¹³ independently done by researchers I -- I'm ¹³ funding of that work, yes. ¹⁴ unfamiliar with before I had seen the AOP. Q. Led to the funding of the work. Okay. And did you see that AOP ¹⁵ And then at some point you presented at a ¹⁶ for the first time in connection with this ¹⁶ conference, and were you presenting on behalf ¹⁷ litigation? ¹⁷ of FDA? Yes. It was published, I A. No. I was meeting with -- it ¹⁹ think, while I was doing the review of the was a conference with shareholders in the ²⁰ literature for this litigation. ²⁰ medications, different shareholders for each Okay. And you mentioned EPA. ²¹ one of the HIV antiviral integrase ²² inhibitors, and we met with them in addition ²² You mean the Environmental Protective ²³ Association? ²³ to the FDA and the World Health Organization. 24 24 Q. Okay. So who asked you to Agency, yes. A. 25

Agency. Agency.

²⁵ attend that meeting?

Page 54 1 ¹ published by -- not an OECD publication but The NIH. A. 2 Okay. So not the FDA? ² an independently published. Q. 3 Q. Okay. And the reason I'm Well, the NIH would -- who had ⁴ asking about AOP 20, you mentioned your heavy ⁴ contacted us. The FDA was there also. metal research just a little bit ago. Q. Right. I understand they were ⁶ there. AOP 20 is about using mercury to induce neurologic effects, correct? My original question was ⁸ whether the FDA ever asked you to do any work The primary compound that is ⁹ in particular on a compound. described in that AOP is mercury, but it also 10 ¹⁰ includes acetaminophen as a common compound A. Right. 11 And FDA has not asked you to do ¹¹ that can also produce the same oxidative Q. ¹² work on a compound, correct? ¹² damage in -- in cells and produce the same 13 ¹³ outcomes. A. Well, multiple organizations 14 ¹⁴ that were -- that were asking for that. Q. Well, the pathway itself has multiple steps, correct? 15 Q. Let me try this again. FDA ¹⁶ didn't invite you to that conference, A. That's correct. 17 Q. 17 correct? And the one that's published 18 that you're relying on uses mercury to induce It's hosted by the NIH. A. 19 the depletion of glutathione, right? Okay. Did you have any contact 20 A. Well, they specifically look at ²⁰ with the FDA other than talking to them at that meeting? mercury and the depletion of glutathione, in 22 addition to the AOP cascade. And the Α. Yes, I did. 23 Q. Okay. What was that? ²³ analysis they conduct is then a weight of the ²⁴ evidence analysis on that AOP, specific to Other people at the -- at the ²⁵ FDA had contacted me, and I had some ²⁵ mercury. Page 57 ¹ correspondence with them about the work we But they include acetaminophen ² as another compound that can produce the same ² were doing. ³ effects as far as the oxidative damage and Okay. Before or after the Q. 4 meeting? ⁴ the interaction with thiol groups and ⁵ specifically with glutathione. A. Both. Q. They do not, Dr. Cabrera, Okay. And it was in regards to include acetaminophen as something that can those compounds --⁸ be the first step to deplete the glutathione 8 A. Yes. 9 in that AOP, correct? -- correct? 10 Did they ever -- ever ask you A. It's not in the group of 11 for -- to provide them a report or any ¹¹ compounds like mercury. It's not -- it's not 12 listed with mercury. specific research? 13 They did ask for the data that 13 Q. Right. ¹⁴ we were -- that we planned on presenting. 14 So the only place that -- if we And this was all with regard to ¹⁵ look at it, and we probably will later today, ¹⁶ the only place we would see acetaminophen is 16 neural tube defects, correct? 17 A. Yes, it was. ¹⁷ in a list -- in that pathway on the third step, I believe. It's in a list of stressors 18 Q. Okay. Back to the -- to the 19 ¹⁹ that once the glutathione is gone because of AOP. 20 ²⁰ the mercury can induce damage in the pathway, Is AOP 20 the only AOP that is ²¹ correct? important to your opinions here? A. Well, in addition, there was That's not correct. It's a ²³ list of stressors that can produce the same ²³ also another publication that came out in ²⁴ regards to the cannabinoid pathway, which was ²⁴ biological effect, molecular and biological

25 effect.

²⁵ also another adverse outcome pathway that was

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Page 58	underlying you saw there were references
² A. And that is oxidative stress.	² for the list of stressors, correct?
³ Q. Do you agree that step one only	A. Yes.
⁴ includes mercury and that step one is to	Q. Did you look at the underlying
⁵ deplete the glutathione so that there's no	⁵ papers?
⁶ glutathione in the system, correct?	⁶ A. Yes, I did.
A. Well, there are other compounds	Q. Okay. And did you see the data
8 listed in addition to mercury that can	8 for why acetaminophen is in there?
⁹ produce those effects.	9 A. Why I'm familiar with the
Q. Okay. And the other compounds	¹⁰ data, yes.
¹¹ are other heavy metals that are not	¹¹ Q. Well, in the published in
¹² acetaminophen, correct?	the literature references, there's nothing
¹³ A. They're not just heavy metals.	behind it, right? It's just acetaminophen is
14 Q. Okay. They're not	¹⁴ in a list of things that can cause
15 acetaminophen in the other compounds that can	potentially cause damage in the setting of
deplete the glutathione, correct?	16 depleted glutathione?
A. Well, acetaminophen can deplete	¹⁷ A. Well, acetaminophen itself can
¹⁸ glutathione, but it's not specifically listed	¹⁸ cause decreases in glutathione.
¹⁹ in the AOP with mercury. It's listed as a	¹⁹ Q. I know you believe that, but
20 stressor in that pathway.	that's not in the AOP, correct?
Q. Let me let me	A. That's not a belief. That's
²² clarify that question because I think I	²² supported by factual, scientific data.
think we're on the same page.	Q. Well, it's Dr. Cabrera, it's
In the AOP 20, which you rely	²⁴ not in AOP 20, is it?
25 on in your report, acetaminophen is not part	25 A. It does deplete glutathione in
Page 59	Page 61
of step one of depleting the glutathione.	¹ AOP 20. It can cause depletion of
² That is not listed as one of the things it	² glutathione.
³ can, correct?	³ Q. Okay. Okay. We're going to
⁴ A. So, in the AOP, it's not listed	⁴ have to look at that because that's
⁵ with mercury in those first set of compounds.	So your testimony right now is
⁶ Q. And then the next step or	6 that AOP 20 says that acetaminophen depletes
⁷ further down the cascade you used the term	⁷ glutathione?
8 cascade, right? It's the pathway?	8 A. Not absolutely, but it
⁹ A. Yes.	⁹ certainly as a stressor, it can decrease
Q. There's once the glutathione	glutathione.
is depleted, there's the stressors, and	Q. And you're saying that AOP 20
there's a list of them, correct?	12 says that?
A. Generally speaking, the effect	A. That as a sucssor
of glutathione can be made worse or can be	14 acetaminophen can decrease glutathione. 15 Okay Did you look into the
caused by the stressors as well. And does it say that in the	Q. Okay. Did you look into the
Q. And does it say that in the	other stressors that are listed in AOP 20
17 AOP? 18 A It describes the effect of the	A. 105, 1 did.
A. It describes the effect of the	Q do you recan ment:
stressors as creating oxidative damage, which	Okay. So furan, you saw mat:
20 is consistent with the same effect that the	A. Puran, yes.
mercury and other compounds cause.	Q. Did you look at the interactive
Q. Dut it doesn't say it in the	Communati
Tion, contect.	A. I III faiiiiiai witti it.
71. It says exactly what I said.	Q. Did you look at the references
Q. Okay. Did you look at the	²⁵ that are actually in AOP 20?

A. Some of them.	¹ also affect glutathione as part of its
² Q. Okay. Do you know why not	² metabolism, just like mercury.
³ every not all the stressors that were	Cabrera Exhibit 1 marked for
4 listed in the reference literature were	identification.)
5 included in AOP 20?	⁵ QUESTIONS BY MR. MURDICA:
⁶ A. Well, because they only did a	⁶ Q. Why don't we mark that, the
⁷ weight of the evidence analysis on mercury.	⁷ AOP 20.
8 Q. How do you know that?	Okay. Is that the AOP that you
9 A. It's evident in the document.	have in front of you, Doctor?
Q. So carbon tetrachloride isn't a	10 A. Yes, it is.
11 stressor in the setting of mercury.	MR. WATTS: Jim, what is the
Is that your testimony?	¹² exhibit number?
A. It's it's listed in the AOP,	MR. MURDICA: It is AOP 20
but the AOP is specific in regards to a	that's cited in this
weight of an evidence analysis for mercury.	MS. KING: It's 1.
¹⁶ Q. Carbon tetrachloride is listed	MR. MURDICA: Exhibit 1, yeah.
17 in the AOP?	MR. WATTS: There you go.
18 A. We should we should look at	MR. MURDICA: We didn't mark
19 the AOP for specific compounds. I don't	anything yet.
remember them all.	²⁰ QUESTIONS BY MR. MURDICA:
Q. Okay. And the outcome	Q. And, Dr. Cabrera, prior to this
because it's an adverse outcome pathway, the	being well, is this is this published
outcome is what in AOP 20?	²³ in peer-reviewed literature?
A. Again, we should look at the	A. Yes, I believe it is.
²⁵ document if you want a specific the	Q. Okay. And where is it?
Page 63	Page 65
¹ specific language, but in regards to learning ² and development	A. 1 I u llave to look.
and development.	Q. Okay. Tou found this offine,
Q. Right.	 though, right? A. It is correct.
In learning and development, you're using that as a marker for autism in	
⁶ your report, correct?	⁵ Q. Not in any particular ⁶ literature citation or anything like that?
⁷ A. It's described in the document	A. Initially I found it online
8 itself, that it can overlap with autism.	I .
⁹ Q. Okay. Your testimony is AOP 20	 Q. Okay. A when I was searching the
of describes in the document that learning	database for adverse outcome pathways.
describes in the document that learning 11 decreased learning can overlap with autism?	Q. Okay. And have you ever been a
12 A. That's correct. I quoted	¹² part of the review for this adverse outcome
that those specific statements in my	pathway?
¹⁴ report.	¹⁴ A. I was not part of the review
¹⁵ Q. And you are relying on AOP 20	¹⁵ for this adverse outcome pathway.
as proof that a pathway exists between	MS. KING: Do you have another
well, it only has mercury in there, but a, I	copy? Is that going to be the case
guess, demonstrative that such a pathway	with all of the exhibits? Because I'm
¹⁹ could exist between an exposure and autism,	going to want a copy so I can look at
²⁰ correct?	it all along.
A. It doesn't only have mercury in	Depending on how we go, I might
there. It has other compounds, and one of	need to ask for a break and get a copy
²³ those stressors includes acetaminophen	²³ made.
²⁴ interacting with the same pathway.	MR. MURDICA: You know what,
And as I'm well aware it can	25 We'll

we'll --

And as I'm well aware, it can

Page 66 Page 68 ¹ normal work outside of litigation? MS. KING: Go ahead. 2 If it's in regards to MR. MURDICA: We'll come back 3 ³ teratogens that can have a detrimental effect to it, that way you have -- you have 4 ⁴ on people, I reckon everyone's entitled to a your own copy --⁵ defense in our -- in our country, but 5 MS. KING: Thank you. 6 ⁶ nevertheless, those compounds are MR. MURDICA: -- when we do. particularly dangerous. QUESTIONS BY MR. MURDICA: O. Right. Q. Let's go back to genetics. We'll come back to this later. And what Dr. Chung was talking ¹⁰ about was whether or not they induce autism, In your -- in your practice, do 11 not whether or not they're dangerous or you treat any human patients? 12 ¹² induce major congenital malformations, Treat, we do not -- I do not 13 ¹³ correct? treat patients. 14 14 Okay. You do not diagnose A. Compounds that can cause patients, correct? congenital malformations and autism are dangerous compounds. A. I do genetic analysis consistent with identifying mutations in 17 Yeah, and that's not -- that's human patients, but I'm not allowed to not what I was asking. diagnose patients. You realize the portion of 20 ²⁰ Dr. Chung's opinion that you were criticizing And that's -- is that because ²¹ was about whether those compounds cause you're not a medical doctor? ²² autism and other effects, not whether they A. It's because I'm not a licensed ²³ cause major congenital malformations, geneticist or medical doctor or medical 24 correct? geneticist. Q. In your rebuttal report, you Well, as autism is represented Page 67 Page 69 as a functional deficit that is correlated ¹ reference Dr. Chung many times. ² with congenital malformations, specifically Do you know Dr. Chung? Not personally. ³ like neural tube defects, those are similar Okay. Have you ever interacted ⁴ in that regard. O. ⁵ with Dr. Chung in any way? Is autism a structural birth Q. ⁶ defect? Not personally. 7 Okay. Is there any reason why A. That's -- it's diagnosed by you would like or dislike Dr. Chung behavioral testing clinically. personally? Right. 10 10 A. No. So it's not diagnosed as a 11 structural birth defect, correct? When you compared Dr. Chung to ¹² defending war criminals, that wasn't from any There are structural defects personal opinion? associated with it, but it's not part of its 14 ¹⁴ diagnosis. MR. TRACEY: Object to the 15 form. Okay. And not every -- not 16 ¹⁶ every compound that induces structural birth THE WITNESS: I was referring ¹⁷ defects also induce autism, correct? 17 to the drugs as -- and the fact that 18 18 they were human teratogens, that they A. That is correct. 19 19 were similar to war criminals in the Okay. In fact, of the -- of 20 ²⁰ the antiepileptic drugs -- of which you fact that they had maimed and hurt 21 believe many cause major congenital people, the chemicals. QUESTIONS BY MR. MURDICA: ²² malformations, correct? 23 23 Is that -- is accusing people That's correct. ²⁴ of defending war criminals something that 24 Only one has been associated

²⁵ you -- is that the way you talk in your

²⁵ with autism to date, correct?

Page 70 Page 72 ¹ time right now? We're currently conducting ² those studies in animal models, but in the --Yes. ³ as far as the handbook for physicians, it was Understanding that you -- I ⁴ specific to valproic acid. ⁴ think you said you can't -- even though you ⁵ can conduct genetic testing, you can't Okay. Are there other ⁶ diagnose anyone; is that right? You can't antiepileptics that you believe cause autism? diagnose a human patient? We're currently looking at Yes. So we run human patients that. 9 Okay. Are there any that you ⁹ for what's referred to as sequencing or Q. resequencing. We also can send out for whole believe so far cause autism? 11 genome, and I do the analysis of that, but I We're still blinded to that ¹² data, and I'm not ready to draw conclusions provide the reports back to whomever is the 13 intended physician or the medical geneticist on it. for diagnosis. 14 Okay. And when you say "we," ¹⁵ you're doing more animal studies on 15 Q. Okay. And I assume you've antiepileptics? never diagnosed anyone with autism or ADHD. 17 17 Is that fair? A. Yes, we are. 18 18 A. We've had patients that have Which antiepileptics are 19 mutations that were consistent with autism included in your studies? 20 Well, valproic acid, in that we identified in our laboratory. addition to -- and I don't have them all in Q. Okay. And you, Dr. Cabrera, ²² front of me, but there's several other never diagnosed a patient with autism or ²³ compounds that we're testing that are also ADHD, correct? anticonvulsant drugs. I don't do diagnosis for 25 Q. Okay. But you can't think of autism. Page 71 Page 73 1 ¹ any of them? Q. Okay. Not just the top of my head. I But the patient herself was --Α. ³ have to have the grant in front of me to tell did have autism. ⁴ you which one of the compounds we're looking Do you know the diagnostic ⁵ at. criteria to diagnose a patient with autism? 6 Q. Okay. Are you doing that at I'm familiar with the DSM for Baylor? diagnostic, but I'm not -- haven't performed the test, nor am I licensed to do such. A. Yes, we are. 9 And who is funding that? Okay. What are the -- what are Q. 10 Right now, it's not funded. the diagnostic criteria for autism? 11 11 Q. Is that -- what portion of the So typically it's -- has to do 12 work you're doing now in -- at Baylor is 12 with focus and attention, repetitive behavior that, is antiepileptic animal studies? and then social communication disorder. I've only had one grant funded And do you know to what extent ¹⁵ any or all of those need -- boxes need to be ¹⁵ in antiepileptic drugs, even though we've ¹⁶ studied it for decades, and none of our ¹⁶ checked in order to render an autism ¹⁷ diagnosis? ¹⁷ funded work right now is in anticonvulsant 18 18 drugs. There's a score system that's 19 19 based on that, and -- again, I'm not a O. Okay. What is your funded work ²⁰ now? diagnostician in that regard. And then the 21 ²¹ last one is that they should have a negative In anti -- the HIV antivirals. 22 ²² effect on the person that has autism. And so Q. Oh, it's what we've talked ²³ meeting all those criteria is enough to ²³ about before? 24 ²⁴ create the diagnosis. But I -- I'm not Yes.

Is that the majority of your

A.

25

²⁵ familiar with the scoring because I don't do

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Page 74
                                                                                                         Page 76
 <sup>1</sup> that in my -- in my regular work.
                                                            pattern of mutations that's known for
       Q. Okay. What do you mean by
                                                            autistic patients at this point?
                                                                      There are some major genes that
 <sup>3</sup> "negative effect"?
       A. That it has a detrimental
                                                          <sup>4</sup> have been associated with autism, and there
 <sup>5</sup> effect on the well-being of the person.
                                                            are also other minor genes that have been
            Okay. So if somebody is a
                                                            shown to interact with the autism risk.
 <sup>7</sup> savant, is that a detrimental effect?
                                                                      Right.
            Well, if it has negative
                                                                      And interaction itself, it's
                                                            still wide open, right, as to what actually
 <sup>9</sup> effects on them otherwise, as far as social
                                                            causes autism genetically, in your mind?
<sup>10</sup> and communication, then that could be an
                                                         11
<sup>11</sup> indication of that.
                                                                       Well, it depends on the
                                                                A.
12
       Q. Okay. And if I asked you the
                                                         12
                                                            particular case.
                                                         13
<sup>13</sup> same questions with regard to ADHD, would you
                                                                O.
                                                                      Right.
<sup>14</sup> give me the same answers; in that you don't
                                                                     It's not a -- it's not a
15 know the exact criteria and you don't
                                                            uniform presentation genetically, even for
<sup>16</sup> diagnose?
                                                            genetically caused autism, correct?
                                                         17
17
       A.
           I don't do the diagnostics for
                                                                       It depends on the case.
                                                                A.
<sup>18</sup> ADHD.
                                                         18
                                                                       Okay. Well, did autism exist
       Q. And you don't know the
                                                            before pharmaceutical compounds existed?
<sup>20</sup> diagnostic criteria exactly, correct?
                                                         20
                                                                       As far as I know, yes.
                                                                A.
                                                         21
            Outside of what's in the DSM, I
                                                                       Okay. There's autism
<sup>22</sup> have not and never plan on performing those
                                                            documented back in ancient Egypt, right?
<sup>23</sup> tests.
                                                                       I'm not familiar with that
            Okay. And you just testified
                                                            record. I'd like to see that document.
<sup>25</sup> about genetic changes that you thought were
                                                                Q. Okay. When do you first know
                                                Page 75
  consistent with autism.
                                                            of autism being diagnosed in human beings?
            Was that following whole-exome
                                                          <sup>2</sup> Not diagnosed.
 <sup>3</sup> sequencing?
                                                                     When do you first know of
       A. We did perform whole-exome
                                                            autism symptoms being observed in human
 <sup>5</sup> sequencing on that -- on that individual.
                                                          <sup>5</sup> beings, in the human record?
             Okay. And you've seen -- have
                                                                A. Well, consistent with a
 <sup>7</sup> you seen point mutations that you thought
                                                            clinical diagnosis, I was only following the
 <sup>8</sup> were consistent with autism?
                                                          <sup>8</sup> literature since probably the -- me
             In this particular case, we saw
                                                            personally, since the DSMs had been in
  a mutation that was in a particular gene that
                                                            development and listed autism and infantile
<sup>11</sup> we then produced a mouse model for, and the
                                                         <sup>11</sup> autism as particular outcomes.
12 mouse model displayed behaviors also that
                                                                     Prior to that, there are
<sup>13</sup> were consistent with autism. And so
                                                         <sup>13</sup> behaviors consistent with what we now think
<sup>14</sup> collectively, we reported that this gene was
                                                         <sup>14</sup> of as autism but not a clinical diagnosis of
<sup>15</sup> associated with core behaviors in the mouse
                                                            autism.
<sup>16</sup> and would be specific for this human.
                                                         16
                                                                      And when you were following --
17
            And then another colleague at
                                                         <sup>17</sup> so how long has that been that you've had
<sup>18</sup> Baylor identified multiple other patients
                                                            some awareness of autism?
<sup>19</sup> with the same mutation, the same gene with
                                                         19
                                                                A. Since -- I think since I was
<sup>20</sup> similar presentation.
                                                            being trained in teratology.
                                                                Q. Okay. And since you were being
       Q. And there's multiple mutations
<sup>22</sup> that have been identified in patients with
                                                         <sup>22</sup> trained in teratology, had you ever looked
<sup>23</sup> autism, correct?
                                                         <sup>23</sup> into thimerosal as a cause of autism?
24
                                                         24
             That is correct.
                                                                A. I did look at heavy metals and
                                                            particularly thimerosal as well.
             And is there any consistent
```

Page 78 Page 80 Okay. And sitting here today, Q. Q. Sitting here today, do you ² do you believe that thimerosal causes autism? ² believe that thimerosal causes autism? Not thimerosal as a particular I haven't looked at it in ⁴ compound, but mercury, as a causative agent, detail enough to know that. ⁵ is associated with the same endpoints that Q. Okay. Can you exclude it as a ⁶ are identified in AOP 20. cause of autism? O. Right. A. I would say that there's -- in So do you believe -- do you regards to vaccination, that that literature believe that mercury induces autism? ⁹ has not supported thimerosal specifically as A. I believe that mercury can a -- as a cause. ¹¹ increase the risk for autism, yes. 11 Did you ever look at all the Q. 12 So mercury can cause autism in thimerosal vaccine literature? 13 a particular patient, correct, in your view? Yes, I did. 14 14 Depending on the exposure, it's Q. Okay. And did you look at it ¹⁵ been shown that mercury exposure can increase prior to that being debunked? the risk for autism. Concurrently. A. 17 17 O. Okay. Can --O. Concurrently. 18 18 So you didn't look at it before A. And that is causative in it was debunked, correct? regards to the AOP. 20 Okay. Can -- so the AOP itself 20 Well. I was familiar with the ²¹ is enough for you to determine causation in study when it came out, and then with, would that instance? you say, this controversy surrounding how the 23 It's not enough to determine ²³ study was conducted, and then the aftermath ²⁴ of that. I was familiar with all that, yes. ²⁴ causation, but it's enough to demonstrate ²⁵ molecular interactions that can produce a Q. Okay. So you know that there Page 81 Page 79 presentation based on biological structure. ¹ were something like 14 studies that initially ² indicated that thimerosal might induce autism And then you, Dr. Cabrera, make ³ the additional leap and say that it's via vaccination, correct? ⁴ causative, correct? A. I'm -- I don't know what the There -- there's no leap there. count is on that. Okay. But you know that at ⁶ Then you would apply Bradford Hill in order some point there were a whole bunch of ⁷ to determine whether there's a -- there's ⁸ causality. studies, whatever number, that people -- some scientists believed indicated that thimerosal So you, Dr. Cabrera, then apply ¹⁰ Bradford Hill as you see it and determine could cause autism, correct? 11 ¹¹ causality, correct? I'm familiar with of that. Α. So -- well, you systematically Okay. And at the time you ¹³ hadn't looked at those, right? ¹³ review the literature and see if -- how the ¹⁴ different factors in regards to Bradford Hill 14 Α. At the time? support causality or not. At -- well, when they were only And you've done that for those studies that had some people, some ¹⁷ mercury and determined that it's causative, scientists, some plaintiffs' lawyers, believing that thimerosal could induce correct? 19 autism, you hadn't looked at those, right? A. I've looked at that for 20 ²⁰ mercury. A. I was familiar with the 21 ²¹ literature --Okay. Have you looked at it ²² for thimerosal? MR. TRACEY: Objection to the 23 Not as thimerosal as a, you

24

25

²⁵ compound, no.

²⁴ know, derivative of a mercury-containing

THE WITNESS: I was familiar

with the literature supporting that

Page 82 position. ² QUESTIONS BY MR. MURDICA: Okay. And did you believe at ⁴ the time that thimerosal could cause autism? Well, I was familiar with the ⁶ fact that mercury could produce neurotoxicity ⁷ and neurodevelopmental toxicity, but I ⁸ wasn't -- specific in regards to thimerosal, ⁹ I wasn't -- I hadn't drawn any conclusions in ¹⁰ regard to -- specifically to thimerosal. 11 Okay. And you know that since 12 then, it's the unanimous opinion of ¹³ scientists that thimerosal does not cause ¹⁴ autism, correct? 15 A. I don't know about the ¹⁶ unanimous decision, but I can say it's generally accepted. 18 Q. Okay. And do you accept that, 19 Dr. Cabrera? 20 I think that it's still unclear ²¹ in regards to the effects that mercury can ²² have. And I know people know now that ²³ they've removed it out of all of the ²⁴ vaccines, but there's not going to be any ²⁵ more data on that. Page 83 So it's still open, and I don't ² think it'll be ever closed completely. O. Do you consider yourself an anti-vaxxer? I do not. Okay. You accept the science as it comes, right? I weigh it as I'm trained to do. 10 Q. Okay. Does maternal fever cause autism? Maternal fever can also 13 increase the risk for autism. Okay. So you keep saying 15 "increase the risk," when I say "cause." Here, you're proposing to tell ¹⁷ the world that acetaminophen can cause autism, correct? A. Well, I've conducted an ²⁰ analysis consistent with causality for ²¹ acetaminophen. I haven't done the same

Okay. And you realize that ² many of the patients that are pregnant that take acetaminophen have maternal fever and ⁴ that's why they take it, right? That's one of the indications? A. I think it's a compound question, but one of the indications for acetaminophen is -- taking acetaminophen is fever. 10 Q. Right. 11 But yet, you haven't done a full study of fever as a causative agent -as a causative exposure for autism, correct? 14 A. I have a proposal to do that, but we have not --Q. And where is that proposal? 17 A. On my computer. 18 O. Okay. I mean --I've sent it off once. I'm A. going to be resubmitting that for funding. 21 Okay. And I guess that's what 22 I was asking. So it's a proposal to get ²⁴ funding to, what, the NIH or something like 25_that? Page 85 Yeah. So when I was in graduate school, we did increase in maternal ³ body temperature as another model for neural ⁴ tube defects and showed that fever can ⁵ produce neural tube defects, and I would like

⁶ to follow up that work with the effect of fever on autism as an outcome.

Okay. In Dr. Cabrera's view, ⁹ what else are you -- what other exposures, if any, are you convinced can cause autism?

Things that's supported in the ¹² literature, fever would be one of them, in addition to heavy metals such as mercury. ¹⁴ And there's also -- and I'd say that the data, at least at this point, is insufficient ¹⁶ but supportive of -- would be small particle, ¹⁷ air pollution particularly, benzopyrene and ¹⁸ some industrial compounds in that -- in those 19 particles.

- 20 Okay. And have you looked at ²¹ any of those in the context of litigation?
- A. I have not. Well, some heavy ²³ metals I have, but not in regards to autism.
 - Okay. In regards to autism or ADHD, have you looked at any other

24

²⁵ causal effect.

²² analysis for fever, but I'm familiar with the

²³ literature on fever increasing the risk for

²⁴ autism, and that can be consistent with a

Page: 22 (82 - 85)

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Page 86
                                                                                                      Page 88
                                                        <sup>1</sup> doesn't include the null typically.
 <sup>1</sup> environmental exposures outside of the
  context of litigation?
                                                                    Okay. And conversely -- so
 3
                                                        <sup>3</sup> that could be a finding that's significant
       A. I have not.
 4
                                                        <sup>4</sup> that shows an effect, right? Because it's
            MR. WATTS: Hey, Jim, we've
 5
       been going about an hour.
                                                        <sup>5</sup> over 1 in the -- in both ends of the
 6
            MR. MURDICA: Yeah.
                                                          confidence interval, correct?
 7
            MR. WATTS: First break?
                                                              A. To clarify, you can have an
 8
                                                        <sup>8</sup> increase in risk, and that would be greater
            MR. MURDICA: Sure, that's
 9
                                                          than 1, or a decrease in risk, and that would
       fine.
10
                                                          be less than 1 --
            VIDEOGRAPHER: Off the record.
11
                                                       11
       10:01.
                                                              Q.
                                                                    Right.
                                                       12
12
                                                                    -- as far as the point
        (Off the record at 10:01 a.m.)
                                                              Α.
13
                                                       13
            VIDEOGRAPHER: The time is
                                                          estimate.
14
       10:22, back on the record. Beginning
                                                              O.
                                                                     And if the confidence interval
15
       of Media 2.
                                                          and the point estimate are all less than 1,
16
                                                          that is a decrease in risk, correct?
   QUESTIONS BY MR. MURDICA:
17
                                                       17
                                                                    That can be interpreted as a
             Okay. Dr. Cabrera, are you
                                                              A.
  ready to proceed?
                                                          decrease in risk.
19
             I am.
                                                                    And it could be interpreted as
       A.
20
                                                       <sup>20</sup> whatever that exposure is is protective
       Q.
             Okay. I'm going to ask you
  some questions about basics of statistics in
                                                          against whatever the effect is, correct?
<sup>22</sup> reviewing some of the articles that are part
                                                                    So, yeah. I mean, effectively
<sup>23</sup> of your report.
                                                       <sup>23</sup> it's whether you're accepting or rejecting a
            Dr. Cabrera, do you believe
                                                       <sup>24</sup> null hypothesis. In that case, you can say,
                                                       <sup>25</sup> you know, we're not accepting, we're
<sup>25</sup> that results need to be statistically
                                               Page 87
  significant to be meaningful?
                                                          rejecting.
             Not necessarily.
       A.
                                                              Q. Right.
             Okay. Are you part of a group
                                                                   And if an exposure has a point
 <sup>4</sup> supporting abandonment of statistical
                                                          estimate and a confidence interval that's
 <sup>5</sup> significance in epidemiology?
                                                        <sup>5</sup> entirely under 1, in that study, in that
                                                          population, it would be -- it would show a
       A. Not abandonment, but just
 <sup>7</sup> clarification inasmuch as when those
                                                          protectiveness of that exposure to the end
 <sup>8</sup> statistics were introduced, they weren't
                                                          effect, correct?
 <sup>9</sup> introduced for the -- for the kind of line in
                                                                    A decrease in risk.
<sup>10</sup> the sand that has been drawn with them. That
                                                       10
                                                                    Okay. Sure.
<sup>11</sup> was not their intention when they were
                                                       11
                                                                   P-value, what does a p-value
<sup>12</sup> introduced.
                                                          need to be to be meaningful to you,
             Okay. In your opinions here,
                                                          Dr. Cabrera?
<sup>14</sup> in forming a causation opinion, are you
                                                                    So p-values generally would be
<sup>15</sup> relying for causation on any results that did
                                                       15 set as a -- as a function of whatever
<sup>16</sup> not achieve statistical significance?
                                                          analysis you're doing, preferably before you
                                                       <sup>17</sup> conduct the analysis. And most commonly,
             I'm relying on the totality of
<sup>18</sup> evidence, and some of that did not achieve
                                                          it's the -- the alpha set it to -- it's
  statistical significance.
                                                       <sup>19</sup> referred to a 0.05. So it's a 5 percent
                                                       <sup>20</sup> false discovery.
             Okay. And just so we
<sup>21</sup> understand, statistical significance would be
                                                       21
                                                              Q. Right.
<sup>22</sup> where a result finds an odds ratio or a
                                                                   That's the statistical
                                                       <sup>23</sup> convention that most people use, correct?
<sup>23</sup> relative risk that does not include the null,
24 correct?
                                                       24
                                                                    Depending on the type of
```

The confidence interval that

²⁵ analysis you're doing. In some cases it may

Page 92 ¹ be lowered depending on the type of analysis came to Baylor on SSRIs. ² you're doing. Q. Okay. You've seen p-values that come Particularly sertraline. Q. A. ⁴ out to be .00001, right? I'm sorry? O. 5 A. Yes, I have. A. Particularly sertraline. 6 6 And that would be more Oh, sertraline. Q. 7 meaningful to you than .05, wouldn't it? Yes. A. 8 It's not a more meaningful. Q. Got it. Got it. ⁹ It's just in regards to whether we're looking And do you recall what the 10 that as a -- as part of our false discovery, conclusion was of your research or your 11 or you're not liable to find that as part of 11 paper? 12 ¹² your false discovery. Yes. We found that it had a 13 And as part of false discovery, teratogenic effect. Specifically we found clefting in the animals. ¹⁴ if your p-value is .1, that would be an ¹⁵ increased chance that you made a false 15 Q. And that was a paper right when discovery, correct? you started your work at Baylor? 17 17 Yeah, it coincided -- I'm not Yeah, you -- it's correct. 18 sure if we published that while we were at .1 -- by convention, .1 Baylor or while we were at UT, just before we wouldn't be a very good p-value, right? 20 Passing judgment, if you set ²⁰ left. I would have to look at specifically ²¹ out in your statistical testing to set it at when we published that. ²² something less than 0.05, generally you would O. Got it. ²³ need to justify that, why you're setting that In the context of litigation, ²⁴ have you ever worked on SSRIs? ²⁴ at .1, so it would depend on the analysis ²⁵ you're doing. A. Yes, I have. Page 91 Page 93 1 1 Q. Okay, sure. Q. Okay. And when was that? 2 A. It's on my CV. I don't have But that wouldn't -- that the exact year. ³ wouldn't be a result that would be very ⁴ exciting to you based on statistical Q. Okay. 5 It's been several years. ⁵ convention, correct? A. A. Depending on the analysis I'm Did you draw any conclusions in ⁷ doing, but generally speaking, particularly the context of litigation regarding SSRIs? ⁸ with tests that you haven't run before, you Yes. We were looking at would start out with an alpha of 0.05. outcomes for developmental toxicity and particularly impacts on congenital Okay. I'm going to ask you ¹¹ some questions about SSRIs. ¹¹ malformations. Okay. And that was for Dr. Cabrera, do you believe sitting here today that SSRIs cause autism? 13 litigation, right? 14 I haven't looked in the A. Yes. 15 15 literature in regards to the SSRIs and Q. And was that for lawyers based 16 16 autism. in Houston? 17 17 A. In part. Q. Do you believe that SSRIs cause 18 18 ADHD? Q. Okay. Was that for Mr. Tracey? 19 19 I haven't looked in the A. In part. ²⁰ literature with regards to SSRIs and ADHD. 20 And what did you conclude in Q. 21 Okay. Did you ever work out -that litigation? Did you find a relationship between SSRIs and developmental outcomes? did you ever work on SSRIs at Baylor? 23 I -- we -- I believe we did We did find support for that, publish a paper. I'm not sure if it was 24 yes. ²⁵ while we were at Baylor or just before we 25 O. And did you render an opinion

Page 94 Page 96 ¹ that SSRIs cause developmental issues? All right. I'll ask you again ² in case you remember it. Yes, I did. A. 3 Yeah. Pozner. Maybe Pozner, And what issues did you say O. ⁴ SSRIs caused? ⁴ Pozner. At the time the major Q. Oh, yes. Reilly -- Reilly ⁶ congenital malformation that was of interest ⁶ Pozner. was congenital heart defects. A. Yeah. Or Pozner Reilly. Yeah, okay. In the context of litigation, Q. ⁹ have you evaluated any other exposures and Dr. Cabrera, do you know if developmental outcomes? your opinion on SSRIs -- you said SSRIs cause 11 ¹¹ developmental defects, correct? Can you repeat the question? 12 Sure. No problem. We had a 12 Yes. A. 13 13 little unexpected phone call there. O. And was that opinion accepted 14 14 In the context of litigation, in court? 15 A. outside of your regular work --As far as --16 16 MR. TRACEY: Objection. Form. A. Uh-huh. 17 17 Go ahead. You can answer, Q. -- have you evaluated any other 18 exposures and developmental outcomes? Robert. 19 19 A. Yes. THE WITNESS: As far as my 20 20 opinion, it's -- there was --Q. And what are those? 21 21 Largely occupational exposures accepted. I think there was also 22 22 and environmental exposures. some -- also another expert was 23 Okay. Have you -- have you 23 rejected, and so overall, that was not ²⁴ ever done work in the context of litigation 24 accepted. ²⁵ on the drug Paxil? 25 Page 95 Page 97 1 A. Yes, I have. QUESTIONS BY MR. MURDICA: You have an understanding that Q. And that was also for you were excluded as -- you were not plaintiffs' lawyers in Houston, correct? determined to be a qualified expert. You A. That's correct. ⁵ were excluded from that litigation, correct? 0. Okay. Was your work on Paxil ⁶ the first work that you did with plaintiffs' A. I was qualified as an expert, ⁷ but my understanding is that based on the lawyers? exclusion of the epidemiologist, the case A. I believe the first work we did was with sertraline. didn't move forward. Okay. And it's all been in Do you know you were excluded part with the same firm that we're sitting in as an expert? I think collectively because of now, the Tracey law firm, correct? 13 ¹³ the exclusion of the epidemiologist, we were No, it's not correct. 14 ¹⁴ excluded. Q. Okay. What other firms has it 15 been with? Q. Okay. So you don't deny that 16 I've also worked with some you were excluded as an expert in SSRI Α. litigation, correct? other firms in our area and then also in 18 MR. TRACEY: Object to the Colorado as well. 19 19 0. Okay. And which firms are form. 20 20 those? THE WITNESS: Yeah. To be 21 21 clear, there were some criticisms Here, Clark -- Clark Love Α. 22 22 rendered in regards to my opinion, but Hutson. 23 23 my understanding is that the exclusion Uh-huh. Q. 24 24

25

to get the particular firm name. It's --

And in Colorado, I would have

was based on the rejection of the

epidemiologist.

Page 98 Page 100 **QUESTIONS BY MR. MURDICA:** Were they on environmental 2 exposures? Have you ever seen the opinion? Q. 3 A. And occupational --A. I've read it. environmental and occupational exposures. When's the last time you read Q. ⁵ it? Okay. And in each of those 6 ⁶ instances where you gave a deposition, were It's been several years. Α. Okay. We'll take a look at it you being paid by the plaintiffs' attorney? Q. Yes, I was. later. 9 And is that the case going back In Paxil, what opinion did you all the way to Paxil, that whenever you've render there? 11 given a deposition rendering an opinion about That it could also increase the an exposure, it has been for a plaintiff's risk of adverse outcome in -- with in utero ¹³ attorney? exposure. 14 14 Q. Okay. So to be clear, A. That is correct. 15 plaintiffs' lawyers hired you in Paxil And in each of those, when ¹⁶ litigation, and you offered an opinion that you've given a deposition being paid by a ¹⁷ Paxil could cause developmental defects, plaintiff's attorney, you've always come to ¹⁸ the conclusion that the exposure caused a correct? 19 defect, correct? A. That's correct. 20 20 Q. Okay. Did you ever testify in To be clear, in the cases I ²¹ reviewed where I didn't support that opinion, court on that? 22 ²² I haven't been deposed on them. I did not. A. 23 Well, let me -- let me ask O. Do you know if your opinion --²⁴ did you ever testify at a deposition about ²⁴ again because I understand what you're ²⁵ saying, but I want to get a clear answer on 25 that? Page 101 Page 99 1 A. Yes, I did. this one. Okay. Do you have a copy of Q. Every time that you've been ³ that transcript? ³ deposed in litigation, it has been when you've been paid by a plaintiff's attorney A. I do not. ⁵ and when you've come to the conclusion that Do you generally -- when you do Q. ⁶ work for plaintiffs' lawyers, do you get ⁶ the exposure caused the -- a defect in a copies of the transcripts afterwards? human being, correct? So I've been paid by Sometimes. Not always. plaintiffs' attorneys to offer my opinion. Okay. Do you keep them? 10 From that long ago, I wouldn't ¹⁰ When I found that there wasn't evidence A. ¹¹ enough, I've never been deposed about that still have it. 12 ¹² opinion. Okay. How about from SSRIs, do 13 you have those transcripts? Other times, I have been 14 A. I do not think I have any of ¹⁴ deposed, and in those cases, they were plaintiff opinions or opinions that I those S -- SSRI transcripts. ¹⁶ submitted because I was asked to by a Okay. When is the last time you testified at deposition before today? plaintiff attorney. 18 My last depositions were just Do you remember my question? 19 in the last few years. I've given some Yes. Α. 20 depositions. What was it? Q.

But not on SSRIs.

Were they on -- were they in

21

22

Q.

A.

²⁴ litigation?

Okay.

Yes.

You were asking me if I had

²² ever rendered an opinion asked by plaintiffs'

²³ attorneys to -- if all of the opinions that I

²⁴ rendered were asked for by plaintiffs'

²⁵ attorneys.

Page 102 Page 104 1 My question was, every time that is, if there is evidence where ² that you've been deposed in litigation, it 2 you have told lawyers that they don't 3 ³ has been in an instance where you're being have a case, but that is confidential, ⁴ paid by a plaintiff's attorney and where 4 that exists, but you may not be able 5 ⁵ you've rendered an opinion that the exposure to disclose it. 6 ⁶ caused an outcome of a defect in a human Are you with me? 7 ⁷ being, correct? THE WITNESS: Yes, and that's 8 So -- and I'm just clarifying what I've conveyed. I can't disclose ⁹ that. that. 10 **OUESTIONS BY MR. MURDICA:** O. Is that a "yes" or a "no"? 11 11 Well, my clarification is I Okay. And I'm just saying, ¹² have rendered those opinions, and the ones ¹² there's nothing you can disclose to show that ¹³ that were at deposition, I was paid by a you've ever rendered an opinion other than ¹⁴ plaintiff's attorney. the exposure caused the defect for a 15 But I've also been asked to plaintiff's attorney, correct? ¹⁶ render opinions, and when I found that there 16 MR. TRACEY: Well, no, object 17 wasn't evidence, then I didn't go to to the form. It's other than ¹⁸ deposition. I wasn't asked to provide a 18 confidential information. 19 deposition in that regard. MR. MURDICA: Okay. I will ask 20 20 Okay. And do you have any it again, Mr. Tracey. ²¹ proof of any kind that you've rendered QUESTIONS BY MR. MURDICA: ²² opinions finding a lack of a causal 22 Q. Is it your testimony that you ²³ connection between an exposure and a -- an ²³ have confidential information that you would ²⁴ outcome in a human being where you haven't ²⁴ be able to show if it wasn't confidential and ²⁵ gone to deposition? ²⁵ that we may be able to get a Court to protect Page 103 1 ¹ or maybe you could provide to the Court Regular conversations --2 ² directly to show that you've ever rendered an MR. TRACEY: Objection to form. ³ opinion for a plaintiff's attorney other than THE WITNESS: Regular 4 ⁴ one that supported their theory that an conversations I have with -- when I am ⁵ exposure caused an outcome in a human being? consulting, right. A. Yes, I have. I provided that QUESTIONS BY MR. MURDICA: opinion confidentially before. There's nothing you can show me or the Court here that that's ever actually Okay. And you have proof of ⁹ that. You -- it's just -- you just can't happened, right? 10 show it to us because it's confidential, A. Well, it's confidential, so I ¹¹ correct? ¹¹ can't -- I can't --12 12 MR. TRACEY: Yeah, Robert. Be A. I could produce proof of that, 13 ¹³ but it's confidential. careful about confidentiality, Robert. 14 QUESTIONS BY MR. MURDICA: Okay. For the stuff that we Yeah. I just want to be clear ¹⁵ are able to discover and that the Court can ¹⁶ see, you've always sided with the plaintiff ¹⁶ for the record, for the Court, because that's ¹⁷ who's ultimately going to read this. ¹⁷ when it comes to an exposure and an adverse ¹⁸ outcome in a human being in litigation, Sitting here today, there's 19 correct? nothing you could show the Court to verify what you just said about ever opining other 20 To be clear, I've only been than the exposure caused the defect, correct? ²¹ asked by plaintiffs' attorneys to render MR. TRACEY: So, Robert, hold ²² opinions in the past. 23 23 Okay. And when you do that on. I want you to be careful about 24 ²⁴ kind of work for plaintiffs' attorneys, do that question, because if there exists

evidence that satisfies that question,

25

²⁵ you seek the permission of UT or Baylor to do

Page 106 Page 108 ¹ it? I have had some Zoom ² interactions with other experts in this I have not. I consult A. ³ independently for that. ³ regard, but not with any other scientists ⁴ in the literature. Q. Okay. Do you know if Baylor or ⁵ UT have a policy about work outside of the Okay. And by other experts, ⁶ universities? you mean other hired experts by plaintiffs? I'm required to file conflict That's correct. A. Q. Okay. Outside of hired experts of interest. Okay. And you did so here, I by plaintiffs, have you discussed your opinions that we're -- that we're talking 10 assume? 11 ¹¹ about today with any other scientist outside I've filed a conflict of of your lab or outside of hired experts? interest with my company. 13 What does that mean, with your And outside of personal? 14 company? Q. Right. 15 15 So my -- I file a conflict of A. I have not. ¹⁶ interest under my company with Baylor. 16 Okay. Have you contacted any O. 17 Okay. So Baylor does know that ¹⁷ regulatory authorities or Teratology Society you are testifying against the entire or Maternal-Fetal Medicine or American industry of manufacturers of acetaminophen, College of Obstetricians about your opinions? ²⁰ correct? 20 I've spoke with an obstetrician 21 Baylor knows that I work for a ²¹ in our laboratory, but outside of that, no. consulting company --Do you think it's important ²³ that maternal fever is treated during 23 MR. TRACEY: Object to form. 24 pregnancy? THE WITNESS: -- that is 25 It is important. working in litigation, not the Page 109 Page 107 1 1 specific cases. Okay. Why is it important? Q. QUESTIONS BY MR. MURDICA: Because fevers have adverse A. So they don't know your actual outcomes during pregnancy if they're not opinion here, correct? controlled. They do not. O. Do they have adverse outcomes Okay. Have you shared your for the fetus? ⁷ opinion here with anyone other than the A. Yes, they can. plaintiffs' attorneys and anyone that they've And what adverse outcomes can Q. given your reports to? those be? 10 Yes, I have. A. Fevers can increase risk for 11 congenital malformations specifically. It's Who is that? O. 12 been widely published in the literature and My laboratory. A. 13 Okay. Outside of your also supported in animal models. ¹⁴ laboratory, have you shared it with anyone Q. And I think you testified 15 else? earlier that fevers can cause autism, 16 correct? A. My wife. 17 Okay. Outside of a personal A. That is correct. 18 relationship, have you shared it with anyone Q. And fevers can cause ADHD? 19 19 else? A. There are studies that support Outside of my laboratory and that, yes. 21 personal relationships, I have not. Q. Okay. And you don't dispute You haven't, for example, 22 it, do you? ²³ contacted any of the scientists involved in I'm not disputing that fevers ²⁴ the studies that are contained in your are dangerous, particularly for --²⁵ report, have you? Q. Okay.

confidencial babyee	to to flocective order
A anyone to have a fever or	¹ A. I brought a rebuttal report. I
² too high of a fever or particularly for	² do have my rebuttal report.
³ pregnant women to have a high fever for a	Q. You have your rebuttal report?
⁴ prolonged period of time is dangerous	⁴ A. Yes.
⁵ Q. What	⁵ Q. Well, I'll mark a copy so you
⁶ A for the mother and the fetus	⁶ can go with an exhibit copy.
⁷ or the embryo.	Dr. Cabrera, you now have in
⁸ Q. What other	⁸ front of you Exhibit 2, which is titled your
⁹ antipyretics would what could treat fever	⁹ rebuttal report.
in a pregnant woman that's available on the	Do you see it?
¹¹ market right now?	¹¹ A. Yes, I do.
A. It depends on when the	Q. Does that look like your
¹³ medication is taken. There are different	¹³ rebuttal report?
¹⁴ contraindications for other antipyretics.	¹⁴ A. It does.
Q. Okay. How about opioids, do	Q. Okay. Is this the last report
¹⁶ you think women should treat fever with	¹⁶ in writing that you've rendered with regard
¹⁷ opioids?	17 to this litigation?
A. I don't think opioids would be	A. Yes, it is.
¹⁹ a good way to treat fevers.	Q. Okay. Right as we started the
Q. Why not?	deposition today, your counsel handed me a
A. Well, one, they're known to be	stack of articles.
²² addictive. That's a potential problem with	Were those provided by you?
an opioid use, particularly with a pregnant	A. Yes, they were.
mother. 25 Okay When you just testified	Q. Okay. And those were since the
Q. Okay. When you just testified	rebuttal report, correct? Page 113
¹ a minute ago about talking to the other	¹ A. Yes.
² plaintiffs' experts in this litigation, I	² Q. Okay. And that you first
³ have a couple of questions about that.	³ reviewed them since the rebuttal report?
When was the last time	⁴ A. Concurrently. I hadn't
⁵ MR. TRACEY: Wait. Wait.	⁵ included them in the rebuttal report when I
⁶ Wait. Wait.	⁶ was reading through the literature, and I
Jim, I thought we had an	⁷ believe one of your criteria was that I
agreement that we weren't going to	⁸ provide all the information that I had
⁹ talk about that.	9 reviewed in my opinion, but they aren't
MR. MURDICA: About experts	specifically referenced, but I was provided.
talking to experts? I'll look at our	Q. Okay. Some of the studies are
agreement. I thought it was about	12 not one of the studies is from this week,
lawyers.	right?
MR. TRACEY: I thought it was	14 A. Yes. 15 O. Okay But the rest of them are
any communication well, so, I was	Q. Okay. But the lest of them are
there, so it's kind of hard to tease	from 30, 20, 15 years ago, correct?
It out.	A. They vary, yes.
WIK. WIOKDICA. All light.	Q. There's no reason you couldn't
I II tillik about tilat allu lilove oli.	have found those before your rebuttal report, correct?
WIK. TRACET. Okay. Okay.	correct.
(Cablela Exhibit 2 marked for	A. Oh, it wasn't a matter of finding them. I had found them. They were
identification.)	²³ just still open on my browser, and I felt it
²³ QUESTIONS BY MR. MURDICA: ²⁴ Q. Okay. Can I have the rebuttal	²⁴ appropriate that I send them all to counsel
	appropriate that I send them all to counsel

²⁵ report? Or did you bring your reports?

²⁵ because I had reviewed them.

Q. Okay. Are they referenced in	Page 116
² your rebuttal report or your other report?	² QUESTIONS BY MR. MURDICA:
A. They're references in regard to	Q. Anything else, Doctor? Oh, you
⁴ some of the other expert's opinion that were	⁴ have a whole stack?
⁵ provided that I hadn't had a chance to	⁵ A. No, just this. Just these two.
⁶ include in my report.	⁶ Q. And the paper on oxidative
Q. Okay. So if we looked in your	⁷ stress from 2019 by an author called Moore.
8 reports, we wouldn't see the citations to the	8 Okay. With those two papers,
9 new articles that were handed to me this	⁹ Dr. Cabrera, can we be satisfied that we have
¹⁰ morning, correct?	¹⁰ everything you relied on up to this point
¹¹ A. I do not think you would see	today?
them, no.	1
	A. I tillik so, yes.
Q. Okay. And your testimony is	Q. Okay.
that you wanted to make sure we had	All right. Is there anything
15 everything you ever looked at, even if you	about Exhibit 2, your supplement report
didn't reference it, correct? Well because I was looking at	supplemental report, that you don't stand by,
A. Well, because I was looking at	that you need to change, that you need to
18 it in response to the expert reports that	revise, that you need to withdraw, sitting
were provided to me that are appropriate,	here right now?
20 that I provide all of the reports that I did	²⁰ A. No.
21 look at.	Q. Okay. All right. If you turn
Q. Okay. So now we can be	22 to the last page of Exhibit 2, that's your
²³ comfortable that we between your reliance	
²⁴ list and everything I was handed this	²⁴ A. Yes.
²⁵ morning, we have everything you looked at,	Q. This is your report?
¹ considered in rendering this, correct?	¹ A. Yes, it is.
² A. Well, I looked at some other	Q. Okay. So first thing I want to
³ stuff last night as well, but	³ ask you about is on page 5.
⁴ Q. Okay. What did you look at	In your supplemental report,
5 last night?	⁵ for the first time you list genes that you
⁶ A. A couple of studies that	say, quote, "interact with acetaminophen."
⁷ were I did print them out, but I haven't	Correct?
8 sent them for counsel yet.	8 A. That's correct.
⁹ Q. Okay. Do you have those with	⁹ Q. Okay. And you start talking
¹⁰ you?	about catechol-O-methyltransferase, right?
11 A. I do.	¹¹ A. That is listed there, yes.
Q. All right. Can I have them,	Q. And I'm going to butcher the
¹³ please?	pronunciation because I don't know this one.
MR. TRACEY: Can we, excuse me,	profitation because I don't know this one.
identify them on the record?	Capicua:
identity them on the record:	71. Capicua.
WIK. WORDICA. Teall, Th	Q. Capicua:
identify them.	Λ. 105.
MIK. TRACET. Okay.	Q. And capicua is sometiming that
WIK. WICKDICA. Dr. Caurcia just	you've studied in at least one study in your
nanded me a paper from 2013 caned	ido, or that I inner has in his ido, correct.
Diocininca et Diophysica Acta. That's	A. 168, it's one tilling we've
the journal article. "Glutathione	studied in the group.
during embryonic development." We'll get copies and mark them	Q. And you say here in your
vve ii get copies and mark them	supplemental report that capicua interacts
²⁵ later.	²⁵ with acetaminophen in a study of

```
Page 120
 <sup>1</sup> acetaminophen toxicity. And you say that on
                                                              Q.
                                                                    Something like that?
 <sup>2</sup> page 5, correct?
                                                                   And this is about -- this
             Just to be clear, I do report
                                                          Exhibit 3 is about hepatotoxicity, which is
 <sup>4</sup> that on a multicenter study that was based on
                                                          liver, correct?
 <sup>5</sup> murine hepatotoxicity that they looked at
                                                                    It is about hepatotoxicity,
 <sup>6</sup> this interaction.
                                                          which I do indicate in the report.
                                                              Q. And this capicua is not
       Q. I'm looking at the sentence
                                                          mentioned in your initial or amended reports,
 8
  "CIC" ---
 9
                                                          only in your rebuttal report, correct?
            Which is capicua, right?
10
                                                                    That is correct.
             Yes.
11
                                                       11
             -- "was reported to interact
       Q.
                                                              Q.
                                                                    How many other genes, if you
<sup>12</sup> with acetaminophen in a multicenter study of
                                                          remember, were mentioned in that -- in the
   acetaminophen toxicity."
                                                          data supplement to this article?
                                                       14
14
            Right?
                                                                    I would have to go through and
15
             That's correct.
                                                          count them, but several.
16
                                                       16
                                                                    Several or a lot?
             And then you cite Beyer.
                                                              O.
       Q.
17
                                                       17
       A.
             Yes.
                                                              A.
                                                                    Several other genes. I don't
18
       Q.
             Okay. Can we mark this,
                                                          know -- what is a lot?
                                                       19
19
   please?
                                                                    Well, hundreds? Tens?
                                                              Q.
20
                                                       20
            (Cabrera Exhibit 3 marked for
                                                                    Not hundreds.
                                                              A.
                                                       21
21
       identification.)
                                                              Q.
                                                                    Okay.
                                                       22
   QUESTIONS BY MR. MURDICA:
                                                                    They're -- in regards to gene
                                                              Α.
23
                                                       <sup>23</sup> interactions, I did report that there were
           Okay. Dr. Cabrera, I marked as
<sup>24</sup> Exhibit 3 is -- well, you tell me what it is.
                                                       <sup>24</sup> 273 genes that were reported to interact with
       A. This is a report by first
                                                       <sup>25</sup> acetaminophen in ASD, and that's from the
                                              Page 119
 <sup>1</sup> author Beyer titled "Multicenter study of
                                                          database, which I previously cited in my
 <sup>2</sup> acetaminophen hepatotoxicity reveals the
                                                        <sup>2</sup> first report.
 <sup>3</sup> importance of biological endpoints in genomic
                                                              Q.
                                                                    Right.
 <sup>4</sup> analysis."
                                                                   Okay. Let's talk about that
                                                        <sup>5</sup> database.
             Okay. And is this what you
 <sup>6</sup> cited as footnote 15?
                                                                   Who hosts that database?
             Yes.
                                                              A. I'd have to look back. Maybe
       A.
       Q.
             Okay. Could you show me where
                                                          in North Carolina, or one of the Carolinas.
  in this exhibit it says that capicua
                                                          I'll have to look back specifically at the
   interacts with acetaminophen?
                                                          study.
                                                       11
11
             I think it's actually in the
                                                              Q.
                                                                    Right.
  data, in the dataset.
                                                                   And what databases are
13
       Q.
             Okay. And where is the
                                                          available, other than that database, if you
<sup>14</sup> dataset?
                                                       <sup>14</sup> want to do this type of research on genes and
15
                                                          interactions?
       A.
             Online. It's in the dataset
16
                                                       16
  here.
                                                              Α.
                                                                    There are numerous databases
17
                                                          for looking at these types of interactions.
             Okay. If we look in the
                                                                    Okay. What databases do
  article, it won't say it anywhere, right?
                                                       18
19
             No, it's actually in the data.
                                                       19
                                                          geneticists generally rely on?
20
             Okay. When is the last time
                                                                    Typically, most geneticists,
       Q.
                                                          and what I teach the geneticists because I
   you looked at the data?
22
                                                          also cover this in my lectures for genetic
       A.
             When I wrote the report.
                                                       <sup>23</sup> counselors, is the use of, like, the Online
23
             Okay. So three weeks ago, a
       O.
24
                                                       <sup>24</sup> Mendelian Inheritance in Man. And not a
   month ago?
                                                       <sup>25</sup> specific endorsement, but that would be one.
```

Page 122 1 particular studies using expression data. So Q. OMIM? 2 ² a lot of it do come from individual studies. Yes, referred to as OMIM. A. 3 Okay. And did you look at How about SFARI? Q. 4 the -- did you know that, that As far as autism genes, it's a ⁵ 200-and-something of the 273 all come from database that's also used. 6 one study? SFARI is? 7 Yes. A. I was aware of that. A. 8 8 O. Right. Q. Okay. And did you look at that 9 Okay. How about ClinGen? study? 10 It is another database that's 10 A. I did. 11 11 Okay. And did you see used, yes. Q. 12 acetaminophen in that study? Okay. This one that you cite Might have to go back and look is not one that's commonly used, correct? 14 This is a database for ¹⁴ at it specifically and what the different exposures were. archiving molecular interactions, where those ¹⁶ are more specific to genetics and the Q. Okay. Is it your understanding ¹⁷ that that study that included more than 200 ¹⁷ presentation of various gene pathologies. Okay. And when you went -genes that are attributed here connected acetaminophen and autism with those genes? ¹⁹ when is the last time you went into this 20 ²⁰ database? Was it when you did this rebuttal The -- this is a data risk 21 report? report in regards to those that were 22 associated with ASD and acetaminophen A. That is correct. ²³ exposure. So that is consistent with what I Q. Okay. Well, I'll ask you if ²⁴ found in the database. ²⁴ you remember; but if not, we'll take a look ²⁵ at it. MR. MURDICA: We'll mark this Page 125 Page 123 1 Do you know what the criteria as Exhibit 4, please. 2 ² is for a gene to become part of these 273 (Cabrera Exhibit 4 marked for ³ genes that you report interact with identification.) ⁴ acetaminophen? QUESTIONS BY MR. MURDICA: They're -- if they're listed as Q. Dr. Cabrera, you have in front ⁶ changing an expression in the database or ⁶ of you Exhibit 4, which is an article by ⁷ physically interacting -- there are different Santos. ⁸ criteria in the database that are identified, Now, if you recall, this is the ⁹ and you can specify what criteria you want to one that's attributed -- to which is 10 use. attributed more than 200 of those genes. If 11 11 you need me -- if you don't remember that it Q. It's changing any expression, 12 right, at all? was Santos, I can show you how we got there. A. You can select whether it's up 13 I reference Santos in my --14 ¹⁴ or down or an interaction. Q. Okay. Q. And when you get to the page -- in my report. A. ¹⁶ where the 273 genes are listed, there's a Okay. So if you take a look at O. this, could you show us where the ¹⁷ link where you can look at the backup for 18 acetaminophen reference is here? that, right? 19 And did you actually look at A. Yes, you can. ²⁰ the -- did you pull this paper and look at 20 Did you do that? Q. 21 21 it --Yes, I did. Α. Okay. Did you see that one of 22 A. Yes, I have. ²³ the 273, the vast majority of them, were in 23 -- when you did your rebuttal Q. 24 report? one study, one paper? Generally, they derive from Yes, I have.

Page: 32 (122 - 125)

Page 126 Page 128 1 Yeah, so this describes the Α. That is correct. 2 ² methodology that I used. It doesn't Okay. And in the database, you Q. ³ specifically indicate acetaminophen. see it says 273 genes, and then there's a Q. But your rebuttal report says little plus sign? ⁵ acetaminophen? A. I do see that, yes. Yes, because I used Okay. Did you click on that ⁷ acetaminophen and applied the methodology in when you were in the database? ⁸ this paper. Yes, I did. Q. If we look through Exhibit 4 Q. Okay. And that's how you got ¹⁰ and all the supplemental materials, we'll to Santos, right? 11 never see a mention of the word No. If you click on the ¹² "acetaminophen." We'll never see the drug, ¹² references, which is two over, it indicates ¹³ there are 35 references supporting those 273 ¹³ the compound, correct? 14 A. As I indicated, I used the genes. And so if you click on those 273, you 15 methodology in this paper and put should see 35 references listed. ¹⁶ acetaminophen into the database and used the 16 MR. MURDICA: Can we mark this 17 ¹⁷ methodology that's described in this paper. as Exhibit 6, please? 18 Q. You signed your name to a (Cabrera Exhibit 6 marked for 19 report that says 273 genes are reported to identification.) ²⁰ interact with acetaminophen and ASD, correct? 20 **QUESTIONS BY MR. MURDICA:** A. In the Comparative 21 Okay. Dr. Cabrera, you now Toxicogenomics Database, yes. have in front of you what's been marked as 23 Q. Okay. And the backup for that, Exhibit 6. ²⁴ in that database, doesn't say the word 24 Do you recognize this? ²⁵ "acetaminophen," correct? 25 A. Yes, I do. Page 129 Page 127 1 Okay. Is this what you would The database does say see if you click the link? ² acetaminophen. If you query acetaminophen, I ³ believe the second hit to come up is autism. A. Yes, it is. And, Dr. Cabrera, my question Okay. The first reference is O. ⁵ is different. ⁵ Santos, correct? A. The backup for that 273, when Yes, it is. you -- in the database is this paper, right? Santos is the reference for 219 A. It's not only this paper. of the 273 genes you're saying interact with (Cabrera Exhibit 5 marked for acetaminophen in ASD, correct? 10 10 identification.) A. That is correct. ¹¹ QUESTIONS BY MR. MURDICA: 11 Q. So 219 of the 273, we looked at 12 12 the article, has absolutely nothing to do Q. Well, let's take a look. Can 13 we mark that as Exhibit 5, please? with acetaminophen in the words on the page, ¹⁴ correct? Dr. Cabrera, you now have in front of you what's been marked as Exhibit 5. A. To be clear, it indicates ¹⁶ xenobiotics, and it doesn't list all of the Do you have that in front of 17 you? ¹⁷ xenobiotics it analyzed in that publication. 18 18 Dr. Cabrera, Santos represents Α. Yes, I do. 19 Okay. Does this look like the ¹⁹ 219 of the 273 gene interactions you're ²⁰ database that you queried online? ²⁰ relying on in this statement in your rebuttal 21 It is a printout from the A. ²¹ report, correct? 22 22 database. A. It does. 23 O. Okay. And Santos does not Okay. And the second line is ²⁴ what you were talking about in this rebuttal ²⁴ contain the word "acetaminophen" anywhere in

²⁵ report, correct?

²⁵ the paper or the supplemental materials as

Page 130 Page 132 ¹ far as you know, correct? None of them say ² "acetaminophen" in the data or the As I indicated, it indicates ³ that they've studied 397 gene environment ³ supplements. ⁴ interactions. And the database indicates Do you disagree with that? A. G says "acetaminophen," and ⁵ that it's inferred and, therein, one of those ⁶ gene interactions would be acetaminophen. ⁶ that I've reviewed that study previously, and ⁷ it says "acetaminophen" specifically in that Okay. Was this page of the ⁸ title and provides dose-responsive evidence database peer reviewed, to your knowledge? of interactions with ADHD and ASD. Not that I'm aware. 10 And you have no proof, other O. G is one of the human studies ¹¹ than it says it's inferred in this database, 11 that we're going to -- well, it's the cord 12 that Santos actually stands for anything to ¹² blood study we're going to be looking at that's throughout your report, correct? do with acetaminophen, correct? 14 Yes, it is. Well, as I -- as I sit here not A. ¹⁵ in front of the database, and I can't pull up 15 Okay. The others, every other one of these, did you pull them? ¹⁶ the Santos data to show you, I would simply ¹⁷ say there are 397 gene environmental 17 A. I did look at them. ¹⁸ interaction pairs that they looked at in 18 Okay. And you never saw the ¹⁹ Santos, and they don't list all 397 of them word "acetaminophen" in any of them, correct? 20 ²⁰ in the report. Yeah, there -- they -- it's 21 ²¹ based on genetic interactions. That is, Right. 22 genes that have been associated with ASD that And, Dr. Cabrera, did you look at any of these other on Exhibit 6 here? ²³ have been associated with exposures. 24 Yes, I did. Right. 25 25 You did? Okay. But those papers don't actually Page 131 Page 133 ¹ stand for that proposition that the genes And did you find any that ² actually had the word "acetaminophen" in ² have been associated with acetaminophen and ³ them? ³ ADHD in the words that are on the page, 4 correct? Yes, I did. A. Okay. Do you know which ones? A. We would have to look at them ⁶ Well, let's -- how about we try the second ⁶ individually. That being said, the database ⁷ indicates that there's -- they're inferred ⁷ one? A. ⁸ interactions based on a gene in a given study Yes. Have you looked at the second or based on a number of genes depending on one, Doan, D-o-a-n? the study. 11 11 Well, all of them indicate, (Cabrera Exhibit 7 marked for ¹² inferred, except for 3, which is G, and G identification.) ¹³ indicates it's not an inferred. That's a **QUESTIONS BY MR. MURDICA:** 14 ¹⁴ mechanistic interaction. Well, let's look at another one 15 just so you feel comfortable that I'm Okay. So if we look at representing it correctly to you. You have ¹⁶ everything except reference 3, we're not ¹⁷ going to find any reference to acetaminophen ¹⁷ in front of you what's been marked as in the publications, correct? Exhibit 7. 19 A. We'd have to look at them Do you see that, Dr. Cabrera? 20 ²⁰ individually, but the -- but the inferred A. Yes, I do. ²¹ versus the mechanistic interactions are --This is what is reference 2 on ²² typically it's based on database analysis of ²² Exhibit 6, which is the reliance list for ²³ your 273 genes, correct? ²³ those interactions. 24 Q. I mean, I have them all. We And what reference study is ²⁵ this? ²⁵ can look at them all.

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Page 134
                                                           <sup>1</sup> expression data shows that there's changes in
       Q. It's reference 2 on the exhibit
 <sup>2</sup> in front of you.
                                                           <sup>2</sup> genes, and those same genes are in this study
             Oh, I see, yes.
                                                             where there's an increased risk for autism.
       A.
             Do you agree?
                                                                 Q. And that's a supposition,
       O.
 5
                                                           <sup>5</sup> right? You didn't go and look at every gene
       A.
              Yes.
                                                            in the database, did you?
 6
             Okay. And this is -- you're
 <sup>7</sup> counting this as six genes that, according to
                                                                       I did not check all 273 genes.
  you in your supplemental -- in your rebuttal
                                                                 Q.
                                                                        You're relying on --
 <sup>9</sup> report, are genes that interact with
                                                                       I did look at them all, and I
  acetaminophen in ASD, right?
                                                             did -- didn't do analysis on them, all of
11
                                                          11 them, but I -- you know, as I -- as I say
              To be clear, that's from the
<sup>12</sup> database that there's -- it's inferred that
                                                          <sup>12</sup> here, I couldn't -- I don't have the list in
   these six genes interact with acetaminophen.
                                                          <sup>13</sup> front of me.
                                                          14
14
             You're relying on the database
                                                                 Q.
                                                                        Okay. Did you look at the
<sup>15</sup> that the database has it right, correct?
                                                             methodology of how the database infers that
                                                             genes are related to something?
       A.
             I am.
                                                          17
17
       Q.
             Okay. Take the time if you
                                                                        Yes, just how I described here.
                                                                 A.
                                                          18
<sup>18</sup> want to look through there. You're not going
                                                                        You looked at their stated
                                                             methodology on their -- in the database?
  to find acetaminophen, but when you're
                                                          20
  comfortable that you can't find it, you let
                                                                 A.
                                                                        Yes.
                                                          21
  us know.
                                                                 O.
                                                                        There's a page that says it,
                                                          22
       A.
             Okay. My reading of this is
                                                             right?
<sup>23</sup> that the genes that we reported in this
                                                          23
                                                                 A.
                                                                        Yes, there is.
<sup>24</sup> genome-wide association study are also genes
                                                                        And what it essentially does is
                                                          <sup>25</sup> it combs the literature for any one of
<sup>25</sup> that have been reported to be changed in
                                                Page 135
                                                                                                          Page 137
                                                           <sup>1</sup> 200 words it -- that in any way correlate,
 <sup>1</sup> expression with acetaminophen.
                                                           <sup>2</sup> relate, associate, any gene to any compound,
       Q.
             Okay. And it says that in
 <sup>3</sup> there?
                                                           <sup>3</sup> exposure or outcome in any way, just in words
                                                             in the English language, correct?
             It doesn't mention
       A.
 <sup>5</sup> acetaminophen specifically, but in another
                                                                        That is the query, but you can
 <sup>6</sup> part of the database, you can look at the
                                                           <sup>6</sup> also then query further and look for specific
 <sup>7</sup> specific gene interactions that are reported
                                                             interactions. So if you want to look at
 <sup>8</sup> that you don't -- you didn't present before
                                                             genes that went up, you can actually look for
<sup>9</sup> me.
                                                             genes that went up.
10
                                                                      If you want to look for genes
             And it's not -- so you're
<sup>11</sup> saying it's not cited in the article, but
                                                          <sup>11</sup> that went down, you can look for specifically
<sup>12</sup> somehow that article still stands for the
                                                             genes that went down.
   proposition about acetaminophen?
                                                                      If you want to look for
14
                                                          <sup>14</sup> physical interactions, mechanistic
              So the genes that are in this
15 article ---
                                                             interactions, you can also look at
16
                                                             mechanistic interactions.
       Q.
             Yeah.
                                                          17
             -- are genes that are -- have
                                                                      Each one of those is an option
<sup>18</sup> changes in regulations in response to
                                                          <sup>18</sup> for the database.
  acetaminophen, and the genes that are
                                                                       This query that resulted in
<sup>20</sup> reported in this article are associated with
                                                          <sup>20</sup> 273, however, was what I described; it was
<sup>21</sup> autism.
                                                             not a more specific inquiry, correct?
             Okay. And the information
                                                                       Yes, it was the general
<sup>23</sup> about their interaction with acetaminophen is
                                                          <sup>23</sup> analysis of interactions.
                                                          24
   not coming from that article, correct?
                                                                       Okay. Now, throughout this
```

It's not, so that's -- the

²⁵ rebuttal report that we marked as Exhibit 2,

Page 138 Page 140 ¹ I believe, you criticized -- most of it is genetic, correct? ² spent criticizing the analysis of Dr. Chung, There -- it's been shown that ³ correct? ³ they're -- they have a stronger genetic ⁴ interaction or a stronger likelihood of being A. That is correct. Q. And you understand Dr. Chung caused by genetics. ⁶ has offered an opinion here that for ASD and And did you look at Dr. Chung's ⁷ ADHD, the predominant cause in any human ⁷ qualifications prior to criticizing her in ⁸ being is genetics, correct? your rebuttal report? That's my understanding. A. Yes, I did. 10 10 And you, Dr. Cabrera, disagree Okay. And you don't have any Q. O. 11 with that, right? of the qualifications that she has, correct? The principles of teratology I don't have her same 13 qualifications. ¹³ indicate that it's genes and environment, ¹⁴ that any exposure that can produce an outcome 14 Q. Right. 15 ¹⁵ can be modified by the genotype or the No board certifications in ¹⁶ background of that exposure. genetics, correct? 17 17 There are human beings with I'm not boarded in genetics. A. 18 ¹⁸ autism and ADHD that have those conditions Okay. Right. ¹⁹ 100 percent because of a genetic mutation, None of the degrees or ²⁰ correct? accomplishments that she has publicly in 21 genetics are held by Dr. Cabrera, correct? They're all -- there are some ²² genes that are what is referred to as A. I don't have the same accolades ²³ necessary and sufficient to cause autism or as her, if you will. ²⁴ autism behaviors in people with those Okay. And you do know that ²⁵ mutations, that it's part of the different Dr. Chung's opinions that she's rendered here Page 139 ¹ types of genes that interact. are consistent with all of the medical As I mentioned earlier, it's ² organizations that have looked at this, ³ oligogenic, some genes that are necessary and correct? ⁴ sufficient in themselves to cause autism, and A. I disagree --⁵ there's also the polygenic and those that can 5 MR. TRACEY: Objection to form. ⁶ modify risk with interactions between THE WITNESS: -- inasmuch as 7 ⁷ gene-gene interactions and gene-environment Dr. -- Dr. Chung's opinions aren't ⁸ interactions. 8 consistent with Dr. Chung inasmuch as And, in fact, in your -- in her own presentations and her work 10 ¹⁰ Exhibit 2, your rebuttal report, you outside of defense work. ¹¹ criticize Dr. Chung in that you say she **QUESTIONS BY MR. MURDICA:** ¹² relies on -- primarily on the most severe I know you -- I know you --¹³ versions of autism and ADHD in her data, well, I'm not going to argue with you about ¹⁴ correct? 14 that. To be clear, I was pointing out Have you seen what the medical ¹⁶ the exclusion of literature in regards to a organizations have said about acetaminophen ¹⁷ clinical diagnosis of autism based on the ¹⁷ and whether or not they relate to autism and ¹⁸ current guidelines as opposed to some other 18 ADHD? 19 ¹⁹ measures of parameters consistent with autism MR. TRACEY: Objection. Form. 20 ²⁰ or consistent with ADHD, that excluding those THE WITNESS: Collectively, my 21 ²¹ is one way to strengthen a genetic understanding is they're still under 22 ²² interaction. review by the FDA. 23 Outside of that, I'm -- you And the implication, is it not, 24 ²⁴ is that you think the more severe versions of know, unless you're speaking to a

25

²⁵ autism and ASD are -- autism and ADHD are

specific medical organization, I can't

	to flocterive order
Page 142	¹ A. Yes, I have.
Comment.	Q. Aren't those more recent than
QUESTIONS DI MR. MUNDICA.	³ 2015?
	⁴ A. Oh, yes.
How about well, let's talk	⁵ Q. They're as recent as 2022,
about ili your field.	6 correct?
Did you see what OTIS said	7 A. Yes.
⁷ about this?	8 Q. And the conclusion that they
A. Thave, yes.	9 have and the reason why nothing has changed
Q. They disagree with you,	
correct?	with respect to acetaminophen is because they disagree with you, correct?
A. Apparently.	
Q. Not apparently, they do,	MR. TRACEY: Object to form. This is not a re {inaudible}
orrect? You've seen it?	This is not a re (maudione)
A. I ve seen it.	deposition.
Q. rean.	THE WITNESS. Team, I don't
And it's not just OTIS is	agree with that. I think it's suit
more than one person, correct:	under review at the FDA. That's my
A. It's a group.	understanding.
Q. It's a group, and the whole	QUESTIONS DT MIK. MURDICA.
group disagrees with you, correct:	Q. Okay. They have not come to
A. I don't know that the whole	the conclusions, publicly or privately, as
group does. Taldift	far as we know, based on the documents you
Q. wen, as a group	reviewed that you have, correct?
A. I can t I can t say mat.	A. I have not seen
Q. As a group, they disagree with	MR. TRACEY: Object object Page 145
¹ you, correct?	to the form.
A. OTIS did put out a position	THE WITNESS: Yeah, I have not
³ piece, and I don't know that it was OTIS in	seen that a public opinion that has
⁴ its entirety, but OTIS did put out a position	changed since the 2015 statement by
⁵ piece to that effect.	5 the FDA.
⁶ Q. And what does OTIS stand for?	⁶ QUESTIONS BY MR. MURDICA:
⁷ A. It's the	Q. You have not seen a public
⁸ Q. Is the "T" teratology?	⁸ opinion or documents that are consistent with
⁹ A. Yes, Obstetrics, Teratology	⁹ your opinion here, correct, from FDA?
¹⁰ Information Society {sic}, I believe.	A. I have not seen that from the
Q. Okay. MotherToBaby?	¹¹ FDA publicly or in their other documents,
12 A. It's part of it.	other than the fact it's still under review.
Q. Okay. And FDA disagrees with	Q. And did you see what FDA said
14 you, correct?	about this as recently as last month?
¹⁵ A. My understanding is FDA is	¹⁵ A. There was a statement last
still reviewing the information.	16 month. I'm not sure I've seen that
¹⁷ Q. Well, have you looked at what	statement.
they've said?	Q. Okay. I'll show you in a
¹⁹ A. Recently as 2015 was the	¹⁹ minute, in the interest of moving this along.
20 recent opinions that they offered, but that	I asked you about OTIS and FDA.
was there's been quite a bit of data since	Did you look at what ACOG has
then.	22 said?
Q. Okay. Dr. Cabrera, didn't you	A. I'm familiar with the ACOG
24 look at documents produced by the FDA in the	24 rebuttal statement.
25 litigation?	²⁵ Q. Right.
nuganon:	Q. Mgm.

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Page 146
                                                       1
           Okay. So you know they
                                                              so I'll come back to that in a minute.
                                                       2
                                                                  MR. TRACEY: It was -- it was
 <sup>2</sup> disagree with your position here as well,
                                                       3
 <sup>3</sup> right?
                                                              the way you asked your question loaded
                                                       4
                                                              with all sorts of arguments that were
       A.
             Consistent with the rebuttal
                                                       5
 <sup>5</sup> statement, I'm familiar with that.
                                                              probably created within the confines
                                                       6
             Okay. And same with the
                                                             of your firm or Johnson & Johnson.
                                                       7
  Society for Maternal-Fetal Medicine, right?
                                                                  Ground your questions in
                                                       8
             I haven't seen the statement
                                                              something factual.
                                                       9
  for Society for Maternal and Fetal Medicine.
                                                                  MR. MURDICA: Sure.
            Okay. Well, let me ask it this
                                                          QUESTIONS BY MR. MURDICA:
<sup>11</sup> way. Have you seen any medical organization
                                                              O. Dr. Cabrera, earlier we talked
12 that agrees with you -- that agrees with your
                                                         about the thimerosal literature and the
<sup>13</sup> opinions here, Dr. Cabrera, as it relates to
                                                         events surrounding thimerosal and the concern
  acetaminophen and autism and ADHD?
                                                      <sup>14</sup> for autism.
15
                                                      15
            I have not seen a statement
                                                                  Do you recall that?
16
                                                      16
                                                                   Yes, I do.
  from a medical organization, no --
17
                                                      17
                                                                   There was a public health issue
       Q.
            Are you --
                                                              O.
18
            -- in that regard.
                                                         with thimerosal that caused children to not
19
            -- concerned by helping the
                                                         be vaccinated because of a scare of autism in
   plaintiffs here you're contributing to a
                                                         the vaccine, correct?
                                                      21
   public health crisis?
                                                                   I'm familiar with that idea. I
22
            To be clear --
                                                         don't know about that endpoint.
23
                                                                   Okay. And that ended up being
           MR. TRACEY: Objection. Form.
24
                                                      <sup>24</sup> not true. I think we talked about that
           THE WITNESS: To be clear, I'm
                                                      <sup>25</sup> earlier, or at least the data has not proven
25
      not -- there is -- there is a public
                                             Page 147
                                                                                                    Page 149
 1
      health concern for safety, and that's
                                                         it, correct?
 2
      the lack of warning on the label.
                                                             A.
                                                                   Fair enough.
 <sup>3</sup> QUESTIONS BY MR. MURDICA:
                                                                   And you know, as a human being
      Q. You're not concerned that by
                                                       <sup>4</sup> in society, that that has had long-term
 <sup>5</sup> being a part of a lawyer movement to scare
                                                         consequences where some people don't want to
 <sup>6</sup> pregnant women about the use of acetaminophen
                                                         vaccinate their children, correct?
 <sup>7</sup> that you can harm them --
                                                                  I'm aware that that has created
          MR. TRACEY: Robert, Robert,
                                                         some vaccine hesitancy in the population.
 9
      don't answer that question. It's
                                                                   So my question is, as a
10
                                                         researcher at an institution like Baylor, are
      nonsensical. It's argumentative, and
11
                                                      11 you not concerned that you are causing
      it's outrageous for a scientific
12
                                                         thimerosal part 2 by rendering an opinion
      deposition.
13
           If you want to ask a question
                                                         like you are here?
14
      grounded in science, that's relevant
                                                                   So there are potential public
15
      to general causation, do it. If you
                                                         health impacts in that regard. I am aware of
16
                                                      16
      want to make speeches, go out on the
                                                         that.
                                                      17
17
      street.
                                                                  MR. MURDICA: Okay. Let's mark
18
                                                      18
           MR. MURDICA: Okay. Well, my
                                                             this as Exhibit 8.
19
                                                      19
      response to that is that he's offering
                                                                  (Cabrera Exhibit 8 marked for
20
                                                      20
      labeling opinions in his -- in his
                                                             identification.)
21
                                                      <sup>21</sup> QUESTIONS BY MR. MURDICA:
      report, Sean. I could cite the pages
22
      to you, but there's several pages on
                                                             Q. Dr. Cabrera, you have in front
23
                                                      <sup>23</sup> of you Exhibit 8, and I just asked you about
      it, so...
24
                                                      <sup>24</sup> whether you had seen a recent FDA statement
          He also, Sean, just testified
25
```

that there is a public health concern,

²⁵ on this topic. You seemed unfamiliar with

```
Page 150
                                                                                                   Page 152
<sup>1</sup> it.
                                                       <sup>1</sup> the link between the drug and
 2
            Have you seen this before?
                                                        neurodevelopment issues."
 3
                                                                  Do you see that?
           I can't say that I have.
 4
            MR. WATTS: What's the date on
                                                                   One second here.
                                                             Α.
                                                       5
 5
       it, Jim?
                                                             Q.
                                                                   Do you want me to give you the
                                                       6
 6
                                                         page?
            MR. MURDICA: It's July 10,
 7
       2023.
                                                                  It's before that. Oh, no --
 8
                                                       8
            MR. WATTS: Thanks.
                                                                   This one here?
                                                             Α.
                                                       9
   QUESTIONS BY MR. MURDICA:
                                                             O.
                                                                   Yep.
                                                      10
       Q. Doctor, if you turn to --
                                                             A.
                                                                   Okay.
                                                      11
                                                                   You have it flagged, I think.
  unfortunately, the pages aren't numbered. I
                                                             O.
                                                      12
                                                                   Yeah. Okay. Yes.
  will -- let me help.
                                                             Α.
13
                                                      13
            And feel free, you can read
                                                                   Okay. You saw that when you
                                                             Q.
  anything you want. My question is going to
                                                         reviewed it --
                                                      15
  be about this paragraph.
                                                             Α.
                                                                   Yes, I did.
16
                                                      16
       A. If we could take a break so I
                                                                   -- during the break, right?
                                                             O.
                                                      17
  can actually read this and do a bio break.
                                                                  Did you know before today that
18
            MR. MURDICA: Totally fine.
                                                         as recently as July 10th of 2023, the FDA
19
                                                         made such a statement?
       Yeah. Yeah.
20
                                                      20
                                                                   I see that this press officer
            MS. KING: Can we go off the
21
                                                         has made this in this article. I hadn't seen
22
                                                         this article previously.
            MR. MURDICA: Yeah. We'll go
23
                                                      23
       off the record.
                                                             O.
                                                                   Okay.
24
            VIDEOGRAPHER: Off the record,
                                                                    So I was unaware of both this
25
                                                         article and that statement.
       11:25.
                                                                                                   Page 153
                                             Page 151
 1
                                                                  Okay. And the statement here
       (Off the record at 11:25 a.m.)
 2
                                                       <sup>2</sup> by an FDA press officer less than a month ago
           VIDEOGRAPHER: The time is
 3
                                                       <sup>3</sup> disagrees with the opinions you've rendered
       11:43, back on the record, beginning
 4
                                                       <sup>4</sup> in this litigation, correct?
       of Media 3.
  QUESTIONS BY MR. MURDICA:
                                                                  Well, what it indicates is, as
 6
                                                       <sup>6</sup> you -- as you've read, according to this
            Dr. Cabrera, are you ready to
                                                         press officer, that the formal tracking
  proceed?
                                                        processes in 2020 closed, and that they
       A.
            Yes.
                                                       <sup>9</sup> failed to turn up solid evidence of a link
            Okay. I had asked you a
<sup>10</sup> question before we took a break. I can ask
                                                      <sup>10</sup> between the drug and neurodevelopmental
                                                      11 issues. And I do disagree with that
11 it again, but in the meantime, did you have a
<sup>12</sup> chance to review what's been marked as
                                                      12
                                                        statement.
                                                      13
<sup>13</sup> Exhibit 8?
                                                             Q.
                                                                  Right.
14
                                                      14
       A.
            Yes, I did.
                                                                 Because you believe you turned
            Okay. And my question for you
                                                      <sup>15</sup> up a solid evidence of a link between
                                                      <sup>16</sup> acetaminophen and neurodevelopmental issues,
<sup>16</sup> was about -- you see it's dated July 10,
<sup>17</sup> 2023?
                                                      <sup>17</sup> correct?
                                                      18
18
       A.
             Yes, I do.
                                                             A.
                                                                  Because there is solid evidence
19
                                                      19
            Okay. And in it, it is a -- a
                                                        of that.
<sup>20</sup> reporter is attributing to FDA Press Officer
                                                                  As of when -- Dr. Cabrera, as
<sup>21</sup> Charlie Kohler an e-mail where FDA has said,
                                                      <sup>21</sup> of what date, based on your review, is there
<sup>22</sup> "While the agency continues to monitor the
                                                      <sup>22</sup> solid evidence of a link between
<sup>23</sup> issue, it closed the formal tracking process
                                                      <sup>23</sup> acetaminophen and neurodevelopmental issues?
                                                      24
<sup>24</sup> in 2020,' said Kohler, because extensive
                                                             A. I would say there's been
                                                      <sup>25</sup> growing evidence since at least 2015.
<sup>25</sup> reviews failed to turn up solid evidence of
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Page 154 ¹ should have changed. But I can tell you that Okay. Since FDA first said --O. ² you referred to earlier in response to a ² the reference textbook, which is considered ³ question of mine that you were aware of an ³ essential for education in the health ⁴ FDA statement in 2015, correct? ⁴ sciences, indicates that that label Yes. ⁵ changed -- or their labeling of acetaminophen 6 changed in 2015. O. And we're both talking about ⁷ the same thing. It's what you can find on Q. And which reference textbook is ⁸ FDA's website that says while there have been 8 that? ⁹ these studies, there's no reason to change 9 A. That's Briggs. 10 ¹⁰ current guidance for how acetaminophen is Briggs. 11 used, correct? 11 And was that with respect to 12 ADHD and ASD or just ADHD? A. That is correct. 13 Initially, it is with ADHD, but 13 Okay. And you're saying right ¹⁴ about then is when there was a solid link ¹⁴ it also includes other neurodevelopmental ¹⁵ between acetaminophen and neurodevelopmental disorders. 16 issues? 16 Q. And when was that? 17 17 I'm saying there's been growing A. That started in 2015. ¹⁸ evidence since then in support of a causative 18 Q. Okay. So in 2015, it included ¹⁹ interaction between acetaminophen and 19 autism in Briggs? ²⁰ neurodevelopmental issues. 20 It didn't include autism 21 Right. initially. It was ADHD initially. 22 And at what point -- is it And that is -- Briggs is a ²³ 2015 -- what was available as of 2015 would textbook that you used? ²⁴ have led you to the conclusion that it causes It is a textbook that I -- that ²⁵ ASD and ADHD? ²⁵ I reference. Page 155 Page 157 A. I would say the authoritative Okay. And do you know what ² Briggs did to come to that conclusion? ² reference in Maternal and Fetal Medicine ³ changed its warning about acetaminophen in They conducted an analysis of ⁴ 2015. So that would be consistent with the ⁴ the literature. ⁵ growing evidence, and that's the same warning And they said that it's causal? O. ⁶ that it still carries to this day. They made a pregnancy summary specific to that in 2015 and highlighted it Q. Well, I'm asking about your ⁸ opinions, Dr. Cabrera. as a fetal risk summary and then described the literature in that regard. And it Based on your review, because 10 you looked at -- we're going to go into all changed from being compatible with pregnancy 11 the stuff that you looked at over lunch, but ¹¹ to human data suggests low risk and fetal 12 you looked at articles from the 1980s, right, ¹² risk and then described the summary of that ¹³ the 1990s, 2000s? You looked at -- you 13 risk. ¹⁴ handed me today something from two days ago, Okay. And is Briggs something 15 right? 15 that you use to make your causation ¹⁶ determination, or did you do that 16 (Witness nods head.) A. Q. At what point in time, ¹⁷ independently? ¹⁸ according to Dr. Cabrera, was there enough I looked because I -- as I ¹⁹ evidence to believe that there was a causal mentioned previously, I do have a specialist ²⁰ relationship between acetaminophen and ADHD in maternal-fetal medicine, and she said to 21 and ASD? ²¹ look at it in the book and see what they ²² said. Like, that would be what would be the A. I would have difficulty ²³ retrospectively telling you as someone that ²³ current guidance for actual medical ²⁴ wasn't following it longitudinally to tell ²⁴ professionals. And so that's what I looked. ²⁵ you when the exact time that these things ²⁵ This is what they get educated with

Page 158 Page 160 And nothing in Briggs says Q. Right. 2 ² that, 2015 or now, that acetaminophen causes Medical professionals which you ³ ADHD, correct? are not, correct? I am not a medical The pregnancy summary ⁵ indicates, "Although the risk is very low, professional. ⁶ use of the drug for several weeks or longer And in your work in teratology, ⁷ has been associated with cryptorchidism, had you ever looked at Briggs before? I've looked up things in Briggs ⁸ decreased IQ, ADHD and other problems in ⁹ neurodevelopment." And "other problems" are before, yes. ¹⁰ largely referenced. Some of them overlap O. Okay. Is that a reference 11 textbook you use in teratology? ¹¹ with autism and including intellectual 12 ¹² disability. For looking up compounds, you 13 can, absolutely. It's online, so it's easy Q. Okay. And so back to my ¹⁴ question. to access. 15 15 O. Yeah. Whether it be in 2015 or today, 16 ¹⁶ Briggs does not say that acetaminophen causes I'm saying in your work, is ¹⁷ ADHD or autism, correct? ¹⁷ Briggs a standard reference for you as a teratologist and has been? A. It says that it has been 19 A. Yes, specific for human associated with and that short-term use ²⁰ exposures because they tend to focus more on suggests low risk, long-term use suggests ²¹ what's the clinical recommendations in risk of, as I just mentioned, cryptorchidism, ²² decreased IQ, ADHD and other problems in ²² regards to patients. ²³ neurodevelopment. Okay. So Dr. Cabrera, for his ²⁴ opinions here, is relying on Briggs summary Q. Okay. Is there a difference ²⁵ of articles in 2015, correct? ²⁵ between association and causation, Page 161 Page 159 A. I included it as part of the Dr. Cabrera? data, their review as well. A. There is. Right. O. Okay. And association is not 4 And that is an underlying part causation, correct? ⁵ of your causation opinion, to rely on their A. That is correct. ⁶ review of articles from 2015, correct? Your opinion here is that I did review their work as well acetaminophen causes ADHD, correct? as part of the literature that I looked at. That is correct. A. Okay. I just want to be clear. Your opinion here is that 10 As part of your causation acetaminophen causes autism, correct? ¹¹ opinion here, you are relying on Briggs' own That is correct. Α. review of the literature in 2015, correct? Briggs, whether it be in 2015 A. I'm simply referencing them as or now, does not say that acetaminophen ¹⁴ authoritative texts. Authoritative texts are causes ADHD or autism, correct? not part of causation. So that's not part of 15 It's not a causation analysis. A. 16 Okay. Thank you. ¹⁶ the causation analysis, but it was part of 17 ¹⁷ the analysis I conducted --Now, let's talk about some 18 Okay. other things that you considered and --Q. 19 19 because I want to know if they're a part of -- in regards to background. A. 20 your causation opinion or just things that O. Right. Because you can look at the you considered. articles yourself. You don't need to rely on I saw on your reliance list ²³ Briggs' interpretation to come up with your ²³ that you looked at documents from the ²⁴ interpretation, correct? manufacturer of Tylenol. That is correct. Is that right?

Page 162 A. Yes. Here, when you're looking at ² acetaminophen and whether it can cause ADHD 2 Q. Okay. And that was your idea, ³ right? ³ or autism, is -- do you agree with me that we I asked for documents in ⁴ don't have the quality of data that would be ⁵ the equivalent of the NAAED we were talking ⁵ regards to preclinical studies. ⁶ about earlier? In other words, a pregnancy Okay. And how do you know that you got everything that was available? registry double-blinded in humans? I don't know that for a fact. A. It's two questions. Which one Okay. So did you ask anyone do you want me to answer? 10 how many pages or how many documents were Q. Okay. Here --11 ¹¹ produced in litigation with respect to MR. TRACEY: Objection. ¹² Tylenol? 12 Compound. 13 13 A. MR. MURDICA: You cheated. He I haven't asked that. 14 14 Okay. Do you know how many gave you that one. 15 pages you did get? MR. WATTS: Objection. The 16 A. I -- all the pages I did get 16 witness is leading Mr. Tracey. ¹⁷ are in my work cited or my reliance list. 17 QUESTIONS BY MR. MURDICA: 18 ¹⁸ Outside of that, I -- I probably haven't seen Q. Dr. Cabrera, with respect to it, if it's not in my reliance. the data available for acetaminophen exposure 20 Okay. So before I ask you any ²⁰ in utero, does a pregnancy -- a ²¹ questions about them, are these things like double-blinded pregnancy registry exist? 22 ²² Briggs that you considered but they aren't ²³ part of your causation opinion, or are they 23 Oh, no, no. For acetaminophen, ²⁴ no. part of your causation opinion? A. Things that I considered Okay. And so we don't have prospective, double-blinded human pregnancy ¹ They're not part of a causation analysis. ² data with respect to acetaminophen, correct? Okay. And in your normal work, ³ you're looking at science, not at company Not that I'm aware. A. ⁴ e-mails or anything like that, correct? Okay. And in the hierarchy of O. Α. That is correct. ⁵ evidence, that would be really high if we had ⁶ it, correct? Company e-mails and deposition ⁷ transcripts don't really elucidate the data A. In the hierarchy of evidence, I that you're considering for causation, ⁸ would -- I would put that just below correct? meta-analysis. 10 That's generally outside the Q. Okay. And below that, what do ¹¹ scope of -- other than e-mails within Baylor, we have? as an institution, I wouldn't normally look 12 Well, any prospective studies at institutions from -- e-mails from other 13 and then retrospective studies. 14 ¹⁴ institutions. Okay. And there's very --15 15 there's differences in prospective studies, Okay. Q. 16 ¹⁶ right? Some are a higher quality than Or other companies. All right. Before we break for ¹⁷ others, right? 18 lunch, I just want to go back to some of the 18 A. There can be, yes. 19 questions I had for you earlier regarding Okay. And whether they're ²⁰ pregnancy -- we talked about a pregnancy controlled or not, correct, makes a ²¹ registry. 21 difference? 22 22 Do you remember that? A. Yes. 23 23 Yes. Do you agree? 24 Clinical trials, for example, I just want to talk to you ²⁵ would be high up on the scale of evidence, briefly about hierarchy of evidence.

Page 166 Page 168 ¹ right? It's -- relatively speaking, ² it's about --A. Well, clinical trials would ³ normally fall in double-blind, you know, MR. TRACEY: Hold on, Robert. 4 ⁴ studies. So those would be high. You don't have to answer personal 5 And generally, in the United financial information about how much 6 ⁶ States, as an ethical matter, we don't money you make. That's not relevant. 7 ⁷ intentionally test drugs on pregnant people, MR. MURDICA: It does go to 8 correct? bias, if it's 100 percent of what he 9 Yeah. To be clear, I think makes, Sean. 10 that's fairly global, that we don't include MR. TRACEY: Are you going to 11 pregnant women in drug testing. let me ask all your witnesses how much 12 12 MR. MURDICA: Okay. All right. their salary is at their places of 13 13 I'll get into this stuff after lunch employment? 14 14 so that the food doesn't get cold. MR. MURDICA: I'm not asking 15 15 All right. Thanks. I don't want his salary. I didn't ask his salary. 16 16 I just asked how it compared to what anybody getting mad. 17 17 VIDEOGRAPHER: Off the record? he's being paid. Could be 18 18 significant, could be insignificant. MR. MURDICA: Yeah. We'll go 19 19 I didn't -- I didn't tell him how to off the record. 20 20 MR. TRACEY: How long is the answer it. 21 21 lunch break? MR. TRACEY: Well, I know, but 22 22 VIDEOGRAPHER: Off the record, you left -- that question is 23 23 11:59. open-ended. I don't know how else 24 24 any, you know, nonnormal lawyer would (Off the record at 11:59 a.m.) 25 25 **VIDEOGRAPHER:** The time is answer that. Page 167 Page 169 1 1 12:48 p.m., back on the record, MR. MURDICA: If I didn't ask 2 2 beginning of Media 4. it open-ended, you'd object. 3 MR. TRACEY: Well, try me and **QUESTIONS BY MR. MURDICA:** 4 Welcome back from lunch, see. 5 ⁵ Dr. Cabrera. MR. WATTS: Are we going to ask 6 Are you ready to proceed? about money at every deposition, or do 7 7 Yes, I am. you want to not do it? I don't care. A. Okay. All right. We're going 8 Q. You decide. to get back into it with some easy ones. MR. MURDICA: I'll pass. 10 I think you acknowledged **QUESTIONS BY MR. MURDICA:** 11 ¹¹ earlier that you're being paid for your time Okay. One of the principles of 12 teratology is to consider all evidence when here by plaintiffs' lawyers, correct? 13 you're trying to make a causation A. Yes, I am. 14 determination, correct? Q. And what's your hourly rate? 15 The totality of evidence, yes. A. 500. A. 16 16 Okay. Do you feel that you Q. Okay. And how much have you Q. charged them so far in this litigation, followed that here? 18 18 ballpark? A. Yes. 19 19 A. I think I had about 200 hours Okay. So there's nothing you O. intentionally didn't consider, correct? or so. Maybe just over 200 hours. 21 21 A. Not intentionally. Q. So over \$100,000, thereabouts? 22 A. Approximately, yes. Okay. In your -- you have 23 Okay. And how does that access to your lab that you were talking ²⁴ compare to your -- whatever you get paid by 24 about earlier, right? ²⁵ Baylor or your lab? That's correct.

Page 170 Q. And in your regular work, Q. Okay. And you didn't do that, ² you -- your primary work, you conduct rodent right? ³ tests, right? A. I have not. We do three things in my Okay. O. ⁵ laboratory that is both genetics, and that A. Well, not in this case, no. ⁶ includes human and animal genetics. Do you anticipate doing that in O. And so we have a human genetic this case, sitting here today? ⁸ side, and we make mouse models of human A. That is not something I planned ⁹ disease, we refer to that as the mouse side. on doing. ¹⁰ And then we also do tissue culture and O. Okay. Have you looked at the ¹¹ records of any person in relation to this ¹¹ produce cellular models of diseases. And ¹² that's -- by and large, it's turned into stem litigation, any human being? 13 ¹³ cell cultures. So we make -- induce Case-specific? 14 ¹⁴ pluripotent stem cells, and we do embryo Q. Yes. 15 cultures or neural cultures. I have not looked at any 16 case-specific. So you work with cells? 17 17 Yes. A. Okay. By the way, earlier you said that somebody told you to look at 18 And you work with rodents, and you do process or -- do you do genetic Briggs, and we talked about that for a while. 20 testing there, or do you send it out? (Witness nods head.) For clinical testing, that gets 21 Who is the person who told you ²² sent to Baylor Genetics. For research to look at Briggs? purposes, we do -- we do research. 23 One of the people in our group. ²⁴ Her name's Jackie Parchem. Okay. And when you were asked ²⁵ to look into acetaminophen here, did you Q. Okay. And what's her Page 171 Page 173 conduct any tests in your lab? specialty? A. She's maternal-fetal health. I have not. ³ She's an -- she's an obstetrician, Okay. You didn't conduct any gynecologist. cellular tests? To be clear, that would be a O. And can you -- I didn't hear ⁶ conflict of interest if I was doing tests the last name. Jackie? ⁷ with acetaminophen while I was being paid. I Α. Parchem. ⁸ would have to file that as a conflict of Q. Parchem? ⁹ interest with Baylor. Yeah. Q. Okay. Can you explain that to Okay. And I believe you said Q. you recognized Briggs as an authoritative 11 me? I don't really understand how that's a ¹² conflict of interest. 12 textbook? 13 A. Because I'm being paid, in A. Yes, I do. ¹⁴ order to do research at Baylor with the Okay. What other textbooks do 15 resources that I -- that I have, I would have you recognize as authoritative? ¹⁶ to file that with Baylor; that I would be So what I was trained in for ¹⁷ using my resources to do research --¹⁷ human development is human embryology is --18 usually they are -- I think that's some --Q. I see. 19 Moore's is the textbook --You can't use your lab to do 20 ²⁰ outside research; is that what you're saying? Q. Moore's. 21 21 A. To do my personal research. -- we use for human embryology. 22 22 Okay. You could have used your Q. ²³ expertise to borrow a lab or rent a lab and 23 And it's the same -- it's a done acetaminophen research, correct? ²⁴ medical school class. It's the same book ²⁵ that they teach both graduate and medical That would be a possibility.

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Page 174
                                                                                                   Page 176
 <sup>1</sup> students in that class and under the -- and
                                                                  MR. TRACEY: That's all
                                                      2
 <sup>2</sup> using the same book.
                                                             privileged.
                                                      3
           So for human embryology, that
                                                                  MR. MURDICA: I'm not going to
 <sup>4</sup> was the book we used for human embryology.
                                                             ask anything else.
       Q.
             Any others?
                                                                  THE WITNESS: Okay.
                                                       6
 6
             Yeah, there were -- there were
       A.
                                                                  MR. MURDICA: I was just asking
 <sup>7</sup> others.
                                                             in the context of the discovery
            Okay. Well, I know you
       Q.
                                                             responses.
 <sup>9</sup> testified earlier that you looked to Briggs
                                                         QUESTIONS BY MR. MURDICA:
<sup>10</sup> as an authority, and you use it in your
                                                                   Okay. And one last follow-up
<sup>11</sup> regular teratology practice. So now we --
                                                      <sup>11</sup> on something we talked about earlier.
12 now we have one more.
                                                                  You remember I showed you I
                                                      <sup>13</sup> believe it was Exhibit 4, the Beyer study,
           Are there any others that are,
<sup>14</sup> you know, your regular teratology books you
                                                         and I asked you about CIC, and you said it
15 look towards?
                                                         was in the supplemental tables online.
       A. I reference Moore, I believe,
                                                                   Oh, I told you this was the
in my report as well, as part of my reliance.
                                                        methodology that we used -- are you talking
<sup>18</sup> I -- I'd have to look at my reliance list to
                                                         about Santos?
                                                      19
<sup>19</sup> see what other texts that I did reference in
                                                             Q.
                                                                   No.
                                                      20
<sup>20</sup> there, but those are -- those are two that I
                                                             Α.
                                                                   It was 4.
                                                      21
<sup>21</sup> refer to regularly.
                                                             Q.
                                                                   Sorry.
                                                      22
       Q. Okay. And just going back to
                                                                   Oh.
                                                             Α.
<sup>23</sup> something earlier, Mr. Tracey objected when I
                                                             Q.
                                                                   3 maybe.
<sup>24</sup> asked about your meetings with other experts.
                                                                  MR. CHARCHALIS: Beyer is 3.
<sup>25</sup> So I'm not going to ask about -- anything
                                                                  MR. MURDICA: 3, okay.
                                                                                                   Page 177
                                                                  THE WITNESS: Okay. Yes.
 <sup>1</sup> about those.
            But did you have any role in
                                                        QUESTIONS BY MR. MURDICA:
 <sup>3</sup> responding to our deposition notice and the
                                                                   Remember I -- this was from
 <sup>4</sup> answers to those?
                                                         your rebuttal report. We were talking about
                                                      <sup>5</sup> I believe it was capicua and CIC in your
       A.
             We went through them.
             Okay. Do you recall answering
                                                        report?
 <sup>7</sup> that you had not interacted with any other
                                                             A.
                                                                   Yes.
 <sup>8</sup> experts in this litigation?
                                                             Q.
                                                                   And I said where is it in the
             Inasmuch as we went through
                                                        study, and you said it's in the supplemental
<sup>10</sup> the -- I -- it was only with the lawyers, and
                                                         tables?
                                                      11
<sup>11</sup> so I think they would be familiar with that,
                                                             A.
                                                                   I said I'd need to check the
12 if that was --
                                                         supplemental tables, yes.
                                                                   Okay. So we had checked
             Yeah. I'm not going to ask
                                                             Q.
<sup>14</sup> about anything that happened, but my
                                                      14 before --
                                                      15
<sup>15</sup> understanding, unless I misread it, is that
                                                             A.
                                                                   Yes.
<sup>16</sup> your answer was that you hadn't interacted
                                                      16
                                                                   -- and we checked again.
with any of the other experts.
                                                                  We don't see it. Is there --
                                                      <sup>18</sup> is there anything else -- other than CIC or
            But that -- we know now that's
                                                        capicua, is there anything else that you
  not the case, right?
                                                      <sup>20</sup> would look to, any names somehow we're
             With the -- with the lawyers
  and on call, we did have -- I have -- I have
                                                      <sup>21</sup> missing?
  spoken with some other --
                                                             A.
                                                                   I -- I'd have to look at the
23
                                                      <sup>23</sup> database --
            MR. TRACEY: Robert, don't say
24
                                                      24
                                                                   Okay. But you --
       anything else.
25
                                                      25
                                                                   -- in front of me and --
            THE WITNESS: Okay.
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Page 178 Page 180 1 I'm -- yes, I am familiar with I'm not asking you to agree. ² it. ² I'm just asking you if there's any other name you would refer to that gene by or --O. Okay. And any causation ⁴ opinion and any data you used to reach the Oh, the name of the gene? ⁵ opinion, one of the principles is it needs to Q. Yeah. ⁶ be outcome-specific, correct? Those are both the gene names ⁷ that we -- we've used. It may have had a Specificity is part of Bradford name before that, but I would -- I'd have to ⁸ Hill in that regard. look that up in the database. O. Yeah. 10 That should be available in And I'm asking you about your ¹¹ Teratology Society and the principles. When ¹¹ GeneCards if you were looking for aliases. Okay. So sitting here today, 12 you render an opinion as a member of that 13 society, it's supposed to be ¹³ you're not telling us that it's definitely in ¹⁴ the tables. You agree it's not in the ¹⁴ outcome-specific, right? ¹⁵ article, but you're also not telling us that Just to clarify, that position ¹⁶ it's in the tables; you just don't know? paper, which, you know, if we're going to ¹⁷ talk about it, we should -- we should have it 17 I would have to look ¹⁸ specifically at the -- at the database and in front of us, but I am familiar with it, in ¹⁹ mine in the database to show you exactly as much as the correspondence on that's Tony ²⁰ where everything is, but the interactions are Scialli, and that position is not a position ²¹ there. of the Teratology Society as a whole. I ²² believe that was part of the public affairs I can -- I looked at them. ²³ I've seen them. I think you're just --²³ committee. ²⁴ you're not in the right place in the Okay. What it means -- well, ²⁵ do you -- did you disagree that you should be ²⁵ database. Page 181 ¹ looking at evidence that refers to the Q. Okay. But you believe you ² either saw CIC or capicua in the database? ² outcome you are opining about? A. You should absolutely look It's in the database. 4 ⁴ at -- look at the outcome. Q. Okay. And not in that article, ⁵ Exhibit 3, itself? Q. Right. I'm looking at -- I -- as we And here, the outcome is ASD or just looked at the article, I did not see ADHD. You have two outcomes you're looking capicua in that article, but it is in the at, correct? A. I did look at those two database. outcomes, yes. O. Okay. All right. Let's talk ¹¹ about one more principle of teratology. Q. Those are the two outcomes that you were asked to look at, correct? You know that the Teratology A. I was asked to look at ASD, ¹³ Society about 15 years ago published guidelines for considering causation in ¹⁴ ADHD and -- as specific outcomes, yes. ¹⁵ litigation, right? Okay. And so according to that A. I mean, if you're asking me if ¹⁶ principle, the evidence on which you base there's a publication about that, I'm aware ¹⁷ your causation opinion should be ASD and ADHD ¹⁸ data, correct? 18 that there's a publication about it. 19 A. Well, I'm not going to say that Right. ²⁰ those principles are the -- are definitive or You've seen it before. It's ²¹ even authoritative in that regard, but if you been shown to you before in litigation, 22 ²² want to talk about those -- what the right? ²³ publication says, then we should have it in 23 Α. I have seen it before. ²⁴ front of us specifically. Okay. Did you look at it

²⁵ before rendering your opinions here?

Well, you don't know? It's --

Page 184 you're a member of the Teratology Society. case that is sealed, I'm not at 2 liberty to discuss. I wouldn't take it upon myself QUESTIONS BY MR. MURDICA: to memorize anything Tony Scialli said. Okay. So I'm just asking you It's not sealed. 5 ⁵ then, do you think that that's what you A. So... 6 ⁶ should consider in rendering a causation O. Do you remember a plaintiff ⁷ opinion? Trujillo, Trujillo? I'm familiar with Trujillo. A. You should consider the 9 ⁹ totality of data. We already talked about Okay. Do you remember now what you were alleging the outcome was? 11 11 I mean, if you want to provide And the totality of data Q. specific to the outcome, correct? case-specific stuff, we can review it. We should -- we should consider Q. Well, what I'm asking you is, ¹⁴ those outcomes and also intermediates of ¹⁴ mental retardation is a different outcome than autism or ADHD, correct? those and then parallel outcomes with those. Okay. Well, you testified in a A. It is. 17 ¹⁷ litigation attributing mental retardation in Q. Okay. So are you going to rely a patient to trichloroethylene exposure, on the outcome of mental retardation in ¹⁹ rendering a causation opinion on autism or correct? 20 ²⁰ ASD? A. I'd have to see the particular 21 case you're referring to. As a different outcome, unless 22 ²² they have overlapping pathology, I would not Okay. You don't remember that? 23 ²³ include it in part of my analysis. I'm -- I would have to see the A. particular case you're referring to. Okay. How about learning disabilities? Q. How many cases have you Page 183 Page 185 testified in for plaintiffs? So inasmuch as there are some ² cases with ADHD and ASD that also include I would have to see the ³ learning disabilities, they would be part of particular case --⁴ an analysis. Too many to remember, right? Q. 5 Α. I have a list of them. Q. But not all -- I mean, we ⁶ talked earlier, right? Someone autistic can Where is it? You didn't O. ⁷ be a savant and they don't have a learning provide it to us. Where's the list? disability, correct? I was told that the information that I was to provide was within the last few A. That is a possibility. 10 years. So you're going to use, and you 11 ¹¹ did use, outcomes that were not the target Q. Okay. 12 ¹² outcome as reliance for your causation And that's what I did provide. Α. 13 Do you have -- do you have a ¹³ opinion? Q. 14 list of all of your testimony you've ever If there's overlap in the 15 done? ¹⁵ presentation as part of what's understood about -- particularly with autism itself or 16 Of course. A. 17 Okay. And where is that? ¹⁷ animal models of autism is not every case of 18 autism is the same, and some of them have On my computer. A. 19 Okay. Okay. So you don't overlap with other pathologies. remember attributing mental retardation to And so if those other 21 TCE exposure? ²¹ pathologies included -- were included, then I 22 ²² would -- then I would often include them as A. I'm --23 ²³ part of the analysis. MR. TRACEY: Objection. Form. 24 24 Is it fair to say that if an THE WITNESS: No. If it's --

if you're referring to a particular

25

²⁵ outcome in a study was a symptom of autism in

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Page 188
 <sup>1</sup> some patients or some animals, you included
                                                                O.
                                                                      Right.
 <sup>2</sup> that in your analysis?
                                                                     But not -- all neurotoxicity
       A. I tried to include the totality
                                                           does not equate to ASD or ADHD, correct?
 <sup>4</sup> of data so that I would be fair in that
                                                                      That's correct. The --
 <sup>5</sup> regard.
                                                           particularly for ASD or ADHD, it would be
             In your mind, in Dr. Cabrera's
                                                           developmental neurotoxicity that would be
                                                         <sup>7</sup> more specific for those outcomes, but I did
 <sup>7</sup> mind, is it -- is it reliable to use
  symptomatic outcomes rather than the target
                                                           consider neurotoxicity generally as well.
  outcome of ASD or ADHD?
                                                                      And even if you, Dr. Cabrera,
                                                           considered only developmental neurotoxicity,
       A. It could be informative if
<sup>11</sup> it -- if it is occurring with other outcomes
                                                         <sup>11</sup> that's still a larger pool than ASD and ADHD,
<sup>12</sup> that are core behaviors of ADHD or ASD.
                                                           correct?
                                                        13
            If it -- if it's occurring as
                                                                Α.
                                                                      There are other endpoints with
<sup>14</sup> an endpoint specifically and without overlap
                                                         <sup>14</sup> developmental neurotoxicity such as neural
<sup>15</sup> of ADHD or ASD, then I would not consider
                                                            tube defects would be evidence of
16 that.
                                                        <sup>16</sup> developmental neurotoxicity that's not ADHD
17
                                                        <sup>17</sup> or ASD.
       Q. Right.
18
                                                        18
            But in Dr. Cabrera's opinion,
                                                                      Right.
                                                        19
                                                                     I think we agreed earlier,
  any study where the outcome was learning
  disability counts towards autism, correct?
                                                         <sup>20</sup> neural tube defects are something totally and
21
                                                           profoundly different than ASD or ADHD,
       A. Is not correct.
                                                        <sup>22</sup> correct?
22
             Why not?
       Q.
23
             Because there are some impacts,
                                                        23
                                                                      Well, I don't know about
                                                                A.
<sup>24</sup> and it's even referenced in the -- in the AOP
                                                         <sup>24</sup> totally different because inasmuch as there
                                                        <sup>25</sup> appears to be some overlap in the molecular
<sup>25</sup> where they indicate that some indications of
 <sup>1</sup> learning disability can be core symptoms of
                                                           pathways, but certainly the -- one is a
 <sup>2</sup> autism or of ADHD.
                                                           phenotypic presentation, and one is a
                                                         <sup>3</sup> diagnostic determination based on clinical
            Right.
           And that's why you think that
                                                           diagnostics.
 <sup>5</sup> AOP speaks to autism, correct?
                                                                       The appearance and the outcome
       A. Well, that's -- not just the
                                                           are profoundly different, correct?
 <sup>7</sup> AOP, but those are part of the OECD
                                                                       I agree with that.
 <sup>8</sup> guidelines for testing, that some learning
                                                                       Okay. Before the break, we
                                                                Q.
 <sup>9</sup> and behavioral effects overlap with autism
                                                            were talking about different levels of
<sup>10</sup> and ADHD core behaviors.
                                                            evidence that are available, and we were
                                                        <sup>11</sup> talking about evidence that could be
11
            Okay. And according to
<sup>12</sup> Dr. Cabrera, that AOP also speaks directly to
                                                            available in humans.
<sup>13</sup> autism and that -- the pathway, correct?
                                                                     I'm going to ask you -- you
14
                                                        <sup>14</sup> focused a lot in your report on animals,
            Yes, because the -- some of the
<sup>15</sup> learning and developmental endpoints do
                                                         15
                                                           right?
<sup>16</sup> overlap with autism, and that's even in the
                                                        16
                                                                A.
                                                                       That's correct.
<sup>17</sup> OECD guidelines. Not just the AOP, the OECD
                                                                       And you work with animals?
                                                                Q.
                                                        18
  guidelines.
                                                                       I work with people, too, but,
                                                                A.
19
                                                        19
       Q. Okay. And according to
                                                            yes.
<sup>20</sup> Dr. Cabrera, any neurodevelopmental toxicity
                                                        20
                                                                       And the animals you work with
<sup>21</sup> also is an outcome that you're looking at to
                                                            are -- do you work with rats or just mice?
<sup>22</sup> attribute causation for ASD and ADHD,
<sup>23</sup> correct?
                                                                Q.
                                                                       The outcomes that you looked at
```

²⁵ any neurotoxicity.

A. I did include in my analysis

²⁴ in mice is any developmental toxicity,

²⁵ correct?

Page 190 ¹ that are consistent -- what's referred to as A. I look for developmental ² toxicity generally, yes. ² consistent with ADHD in the animal model. You included in your review Q. You look -- right. ⁴ articles that really had anything to do with You have -- you have guidelines ⁵ toxicity in a -- in a mouse embryo, right? ⁵ that you believe are behaviors consistent ⁶ with those, but you can't diagnose a mouse So my approach as a ⁷ with ADHD or autism, correct? ⁷ teratologist was to look at what Wilson ⁸ referred to as the four manifestations of Right. So clinical diagnosis ⁹ deviant development, and those include of ADHD or autism requires a clinical diagnosis, and we don't do that type of ¹⁰ congenital malformations in addition to ¹¹ functional deficit. ¹¹ assessment on the animals. We do 12 neurobehavioral, behavioral testing on them. And it may also include death ¹³ as a potential outcome, which would be the 13 Q. Right. ¹⁴ most severe form of that -- of toxicity. 14 And those are different Q. For ASD and ADHD in particular, ¹⁵ techniques developed over time that ¹⁶ what outcomes were you looking for in the ¹⁶ researchers like yourself believe are ¹⁷ mouse model? ¹⁷ consistent with neurodevelopmental behaviors, Well, part of looking for these right? 19 outcomes is understanding the study designs I'd say they're generally ²⁰ accepted that these behaviors parallel what and what information is available in there. As an example, you have to we see in the human with similar exposures. ²² examine also maternal toxicity. So you have Q. Well, in fairness, humans ²³ to consider maternal toxicity, even though ²³ aren't burying marbles in tanks, correct? ²⁴ your -- your question may be, What's the They could, but it -- as a ²⁵ outcome in the offspring, ADHD or ASD, you ²⁵ normal behavior, burying is perhaps something Page 191 ¹ also have to consider maternal toxicity as that people and animals may have shared in ² one of those factors. ² the past, but not something that we commonly ³ engage in anymore. So there are -- there are Q. You're not looking at human ⁴ different levels of toxicity because the ⁵ maternal system is providing the environment, ⁵ beings who are repetitively -- repetitively ⁶ grooming or nest-seeking or burying marbles, ⁶ so you have to consider other types of ⁷ toxicity when you're looking at a particular correct? ⁸ outcome. So we do look at repetitive A. behaviors in humans. That's part of a What specifically are you looking for in the mouse to look for autism? clinical diagnosis. So that is part of it, 11 11 actually. So typically we do ¹² neurobehavioral testing in the mouse to look But in regards to specific ¹³ for what's referred to as core autistic ¹³ behaviors of nest-seeking or marble burying, ¹⁴ that's not part of the human clinical ¹⁴ behaviors. 15 diagnosis. And in the mouse, since they 16 ¹⁶ can't talk to us, you can't actually O. Right. ¹⁷ diagnosis a mouse with autism, correct? 17 And, by the way, is ¹⁸ nest-seeking in the rodent model a measure They do vocalize, but it's for ASD or ADHD? ¹⁹ supersonic, so we can't hear them, but we do ²⁰ not use that as part of our diagnosis like In their recognition of ²¹ things -- so, like, socialization is part of you would with a human patient. ²² the ASD or core behaviors. And so disruption Q. And it's the same thing with ²³ in what is partially thought as the olfactory

So we do neurobehavioral ²⁵ testing on them, and we look for behaviors

²³ ADHD, right?

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²⁴ system is -- can be related to that, in that

²⁵ the mouse, unlike the human, which is largely

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Page 194
                                                               <sup>1</sup> better question, because that was a good
 <sup>1</sup> visual, the mouse uses smells in order to
 <sup>2</sup> recognize where it belongs and new people --
                                                               <sup>2</sup> point.
 <sup>3</sup> or new mice, in this case. As we might
                                                                           Our hypothesis, your
 <sup>4</sup> recognize somebody visually, they recognize
                                                               <sup>4</sup> hypothesis, is that those behaviors translate
                                                               <sup>5</sup> in some way to neurodevelopmental outcomes --
 <sup>5</sup> it as smell.
             So it's part of an assessment
                                                               <sup>6</sup> neurodevelopmental behaviors in human beings,
                                                               <sup>7</sup> right?
 <sup>7</sup> for their social behavior, which would be an
 <sup>8</sup> important core behavior for the -- for the
                                                                            So what we do in -- what I've
                                                                 done for the majority of my career is to make
   mouse.
10
                                                                 animal models of human disease. And part of
        Q.
              That answer was about
                                                              <sup>11</sup> making those models of human disease is to
<sup>11</sup> nest-seeking?
              Yes, in order for them to --
                                                                 see if the animal behaviors any way parallel
        A.
13
                                                              <sup>13</sup> what we would find in human behaviors, and we
              So according to Dr. Cabrera,
<sup>14</sup> nest-seeking is a relevant behavior in the
                                                              <sup>14</sup> do find some parallels in that regard.
   mouse model for autism and ADHD, right?
                                                                            Right.
              Well, it assesses a behavior in
                                                                           But the behaviors that the
^{17} the mouse that's part of social -- a social
                                                              <sup>17</sup> animals exhibit are not identical behaviors
   behavior. So you're testing a social
                                                                 that are -- that human beings exhibit,
   behavior of the mouse.
                                                                 correct?
20
              So if you have a litter of mice
                                                              20
                                                                            Neither -- the diagnosis
<sup>21</sup> that are more nest -- are nest-seeking more
                                                              <sup>21</sup> criteria is not the same as would be used
<sup>22</sup> than normal, you would say that's an autistic
                                                              <sup>22</sup> clinically for a clinical diagnosis in
<sup>23</sup> or ADHD signalling behavior or something like
                                                              <sup>23</sup> humans. It does -- it is different with the
24 that?
                                                              <sup>24</sup> animals.
              So you could go either way. So
                                                                      Q. And you agree that the animal
                                                    Page 195
                                                                                                                  Page 197
 <sup>1</sup> if they spent too much time there, this could
                                                               <sup>1</sup> model, in all aspects, not just
                                                               <sup>2</sup> neurodevelopment, does not translate directly
 <sup>2</sup> be associated with anxiety. If they didn't
 <sup>3</sup> spend any time there, then this could be a
                                                               <sup>3</sup> to humans in many cases, right?
 <sup>4</sup> problem with their social behavior. So you
                                                                            There are -- there can be
                                                               <sup>5</sup> differences, both by differences in species.
 <sup>5</sup> have to interpret the data as it comes.
               And when you first started
                                                               <sup>6</sup> Thalidomide is the classic example inasmuch
                                                                 as it had a profound effect in humans, but it
 <sup>7</sup> doing these experiments on mice, did these
 <sup>8</sup> behavioral beliefs and tests in mice exist?
                                                               <sup>8</sup> was initially missed in animals. It was only
                                                                 after they retested in a sensitive rabbit
               They've evolved over time.
                                                              <sup>10</sup> species that they found -- they found the
               And do you agree that those
<sup>11</sup> behavioral observations are really theories
                                                              11 same effect.
<sup>12</sup> because you can't diagnose and talk to the
                                                                           So there can even be
<sup>13</sup> mice?
                                                              <sup>13</sup> species-specific differences that have to be
                                                              <sup>14</sup> considered, and they can be different between
               Well, just to clarify, a theory
<sup>15</sup> is a very strong word in science, and I would
                                                              <sup>15</sup> different species.
<sup>16</sup> say that there -- our understanding of those
                                                                      O.
                                                                            One does not assume that what
<sup>17</sup> behaviors, that they are part of the social
                                                              <sup>17</sup> happens in an animal is going to happen in a
<sup>18</sup> behaviors in the animals. And I don't think
                                                              <sup>18</sup> human or vice versa, correct?
<sup>19</sup> that's theoretical. I think that's part of
                                                                            Yeah, you can't just assume
<sup>20</sup> just the reality that they -- that they exist
                                                              <sup>20</sup> based on a singular dataset. You need to
<sup>21</sup> in.
                                                              <sup>21</sup> look at the totality of the data, and you
                                                              <sup>22</sup> build strength when you start to see effects
              Our interpretation of those is
<sup>23</sup> certainly open as far as what that means and
                                                              <sup>23</sup> across multiple species, or particularly even
```

how we interpret their behaviors.

Q. I guess that -- let me ask a

²⁴ across multiple kingdoms in biology when you

²⁵ start to see similar effects. This builds

Page 198 ¹ strength that a similar outcome will also ¹ behavior on an outcome, like ASD and ADHD, ² after an exposure in a pregnant mouse, ² occur in humans. ³ studies that are examining effects on adult Okay. So if you're looking at ⁴ an outcome in an animal model for ASD or ⁴ mice are not directly on point, correct? They may be informative on ⁵ ADHD, what is the most -- most direct, best ⁶ evidence you can come up with in an animal ⁶ concentrations or mechanism, but they're not ⁷ going to be necessarily informative on the ⁷ model? outcome, the specific ASD or ADHD outcome. Well, there's two parts to that ⁹ in my work. And so one is that to look at Q. Okay. Let's talk now about ¹⁰ the behavior, so we have the behavior human studies and acetaminophen. ¹¹ analysis, then we compare to what's In order for an in utero ¹² considered as kind of a core set. ¹² exposure to happen in a human, the exposure ¹³ has to first be -- the mother has to take And in my work, it's typically ¹⁴ compared to valproic acid. So we would ¹⁴ acetaminophen, right? You agree? ¹⁵ compare the core behaviors to valproic acid There's, like, four steps here. ¹⁶ exposures in the animal. I'll see if you agree with them. 17 17 And then we would also do So there is some background of ¹⁸ pathology on the brains of the animals in acetaminophen exposure in the general ¹⁹ addition to, if available, functional population, and it has to do with ²⁰ genomics, that is gene expression studies, or environmental exposure. And so there's an ²¹ metabolomics to look at the particular active underlying exposure initially. Q. Dr. Cabrera, your causation molecules in the brain. 23 And the behaviors you would be ²³ opinion here is focused on women who actually ²⁴ looking for in an autism model are what? ²⁴ ingest pharmaceutical acetaminophen, correct? A. So the same core behaviors that A. That is correct. Page 201 ¹ we might see in humans. So differences in Okay. So the pregnant woman ² social interactions, repetitive behaviors. ² first takes acetaminophen, right? In the ³ And so we're looking for this core set of --³ mouth? ⁴ referred to as autism behaviors in the mouse, A. Predominantly. There is also ⁵ and there are representative tests for that. ⁵ IV indications, but, yes, predominantly. They're very specific in the Your opinion is about pill ingestion predominantly, correct? ⁷ mouse, though, right? One is -- the repetitive A. I haven't been asked for ⁹ behavior is grooming, the social behavior is case-specific as far as exposures, but we're -- the exposure happens, and there are ¹⁰ either being around other mice or not. 11 Right? ¹¹ currently two routes of exposure commonly. I ¹² think there's also a rectal exposure as well, So one example of a social ¹³ but the majority of them, the vast majority ¹³ behavior would be referred to as a ¹⁴ three-chamber test, or what we call the ¹⁴ of them, would be an oral exposure. ¹⁵ Jackie box, where the animal -- we see if it The human exposure studies ¹⁶ prefers or doesn't prefer to be around other ¹⁶ where it specified what it was, it was pill ¹⁷ animals, which would be a social behavior. ¹⁷ ingestion, correct? 18 Predominantly, yeah, it's going ¹⁸ And there are different types of social 19 ¹⁹ behavior. to be pill ingestion. Okay. The first stop is --And what's currently ²¹ where the body takes on any acetaminophen is ²¹ recommended is to use multiple tests per ²² behavior -- or per core behavior to ²² in the small intestine, correct?

23

24

25

Q.

²⁴ those behaviors.

²³ strengthen the information you have about

Q. And if you're trying to gather

As far as absorption, yes.

Absorption.

Yes.

Page 202 Then it goes to liver, correct, I have looked at fetal brain ² in the mother? exposure in the animal models, and I have cited that in my report. Well, in -- yeah, as far as ⁴ metabolism goes, it goes into a particle, I was talking about human. ⁵ it's referred to as a chylomicron, and then As we've already indicated, ⁶ that would end up in the liver. those studies would be unethical. Q. Okay. Whatever is not Q. And all I'm doing, for the ⁸ metabolized by the liver is now in the blood record, is clarifying what we have and what ⁹ in the mother, right? we don't. Fair enough. It -- yeah. So We don't have any study or data ¹¹ it's going to go into circulation as well. ¹¹ that shows the availability in the fetal ¹² brain at this -- at this point in time Into circulation. 13 ¹³ because of ethics and things like that, fair? And in circulation, that is the ¹⁴ first time it has access to the placenta, Yeah. Just to be clear, I'm 15 fairly sure that's, like, even against the 16 ¹⁶ law in Texas. But with that being said, that So within circulation, yes, it ¹⁷ would have access to the placenta. ¹⁷ data doesn't exist. 18 Okay. It has to cross the Q. Right. 19 19 placenta, right? For any drug. A. 20 20 But we have it in the mouse In order to have access, which O. 21 model. ²¹ we refer to as access in teratology, it would ²² have to cross the placenta. We do have it in animal models. Α. 23 Q. In order to have access to the Q. Right. ²⁴ baby, we're through the mouth, small 24 All right. I'm going to stick ²⁵ with humans for a while. ²⁵ intestine, metabolized by the liver, into the Page 205 ¹ bloodstream, it has to cross into the One of the database studies you ² placenta, correct? cite is Avella-Garcia. And that's an autism study, right? No. I'd say as far as first or ⁴ second-pass metabolism, I have to look A. Yes, it is. ⁵ specifically at that, but that's at least in O. Okay. And you rely on this to ⁶ part correct, yes. support your causation opinion, right? A. I have, yes. Q. Okay. And then next to ⁸ actually access the baby, it -- the brain, 8 MR. MURDICA: We'll mark it as ⁹ right, which is what you're talking about in Exhibit 9. 10 ¹⁰ this opinion, it has to cross the blood-brain (Cabrera Exhibit 9 marked for ¹¹ barrier, right? 11 identification.) A. Acetaminophen readily crosses QUESTIONS BY MR. MURDICA: ¹³ the blood-brain barrier. So if it has access Okay. This one was from -well, you have in front of you Exhibit 9, ¹⁴ to the baby, it will have access to the 15 brain. right, Dr. Cabrera? 16 16 Α. Right. Yes, I do. 17 All of those things have to Okay. And that's the O. ¹⁸ happen before it makes it to the fetal brain, Avella-Garcia study, right? 19 19 correct? A. It is. 20 20 That is correct. A. Q. This is the one you cited in Okay. And you haven't -your opinions, fair? ²² you've cited various studies, but you haven't I believe so, yes. A. ²³ cited anything that directly measures the From 2016? Q. ²⁴ availability of acetaminophen following that 24 A. Looks correct.

²⁵ exposure route in the fetal brain, correct?

Okay. So this was at the point

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Page 206
 <sup>1</sup> that you already formulated an opinion that
                                                         do what we knew and when we knew it?
 <sup>2</sup> acetaminophen could cause autism and ADHD,
                                                              MR. MURDICA: I'm not doing
 <sup>3</sup> right?
                                                         that. I'm -- Sean, I'm asking him
      A.
            As I indicated, there was
                                                         questions about general causation.
                                                              MR. TRACEY: No, you're not.
 <sup>5</sup> growing evidence of that since 2015.
      Q. I think you said earlier
                                                         You're asking him questions about when
 <sup>7</sup> that -- well, correct me if I am wrong. I
                                                         anybody could have known that Tylenol
 8 thought you -- your causation of -- you
                                                         caused autism.
 <sup>9</sup> believed that it was causal as of 2016, I
                                                              I'm happy to play that game
<sup>10</sup> thought you said.
                                                         with your experts, if you want, but I
11
           Is that not right?
                                                         thought this was a general causation
12
            I hadn't done this research in
                                                         deposition.
<sup>13</sup> 2016.
                                                              MR. MURDICA: Okay. I'm not
14
      Q.
            Okay. So sitting here today,
                                                         going to argue on the record with you,
15 you can't say when, in Dr. Cabrera's mind,
                                                         but all I asked him to say is he's not
<sup>16</sup> this became causal until -- except for 2023,
                                                      <sup>16</sup> going to say when somebody could have
                                                      <sup>17</sup> known it, and he didn't answer that
17 right?
18
            That's when I did the causation
                                                         question.
                                                      19
  analysis. So I couldn't say I had determined
                                                              MR. TRACEY: Well, I know,
<sup>20</sup> causality before then because I hadn't done
                                                         because he hasn't been asked that
  that analysis.
                                                         question, and he hasn't developed that
22
      Q. And you couldn't say anybody
                                                         opinion. That's a phase II opinion.
<sup>23</sup> could have determined causation before then
                                                         He may very well have that opinion
<sup>24</sup> because you didn't do that analysis, right?
                                                         when we finish depositions.
      A. Well, I can't offer my opinion
                                                              MR. MURDICA: Okay. Well, let
                                             Page 207
                                                       1
 <sup>1</sup> about what other people did because I'm not
                                                             me try and --
                                                       2
 <sup>2</sup> other people.
                                                                 MR. TRACEY: I just -- it just
      Q. But you, Dr. Cabrera, when I
                                                             feels like it's part of the phase I.
 <sup>4</sup> asked you, you -- based on the totality of
                                                         QUESTIONS BY MR. MURDICA:
 <sup>5</sup> the evidence that you've reviewed, you can't
                                                                  Sitting here today,
 <sup>6</sup> say there was enough there in 2022, right?
                                                       <sup>6</sup> Dr. Cabrera, do you have any opinion on when
       A.
            2022?
                                                       <sup>7</sup> the relationship, in your view, was causal,
      Q.
                                                         one way or another?
            Yeah.
      A. I wasn't looking at the
                                                             A. I only have my personal
  question in 2022.
10
                                                         experience in that when I conducted the
                                                      <sup>11</sup> analysis, I found it to be causal. I can't
11
      Q. Right.
                                                      12 say when other people should or shouldn't
           But based on what you know
<sup>13</sup> today, you -- you're not going to sit here
                                                      <sup>13</sup> have found it.
<sup>14</sup> and say there was enough evidence in 2022 for
                                                             Q.
                                                                  In 2023, correct?
                                                      15
  this to be causal, right?
                                                                  That's correct.
16
                                                      16
           MR. TRACEY: Jim, let me just
                                                                  Okay. Now, on Exhibit 9, so
17
       interrupt you for a second.
                                                      <sup>17</sup> this was a database study in human beings,
18
                                                      18
           Are we doing liability
                                                         right?
19
                                                      19
      depositions? Because if we are, I'm
                                                             A.
                                                                  I'm not sure what you mean by
                                                      <sup>20</sup> "a database study."
      happy to join with your experts, but I
21
      thought this was a general causation
                                                                  Okay. There were maternal
22
      deposition.
                                                      <sup>22</sup> interviews at 12 and 32 weeks during
23
                                                         pregnancy, correct?
           MR. MURDICA: It is. And
24
                                                      24
       that's not what --
                                                                  That is correct.
25
                                                      25
           MR. TRACEY: So we're going to
                                                                   Okay. And there were about
```

```
Page 210
 <sup>1</sup> 1,300 participants?
                                                              1,300 children that are behind that score,
             So there was 2,644 mother-child
                                                            <sup>2</sup> correct?
 <sup>3</sup> pairs. So as a -- as a child outcome, there
                                                                   A.
                                                                         You may want to ask that
 <sup>4</sup> would be 1,300.
                                                              question again.
             Okay. And if you look at
                                                                   Q.
                                                                         Sure.
                                                            6
 <sup>6</sup> Table 3, which is on page 1992 in the
                                                                        You're looking under males --
                                                            7
 <sup>7</sup> journal, these are the outcomes. And what
                                                                   A.
   you cite in your report is for males --
                                                            8
                                                                         -- with persistent use?
                                                                   Q.
                                                            9
            Are you on Table 3?
                                                                         (Witness nods head.)
                                                                   A.
                                                           10
10
             Yes, I am.
                                                                   Q.
                                                                         And is 21. That's 21 boys,
11
                                                           11
       Q.
             Okay.
                                                              correct?
12
                                                           12
            -- for males with persistent --
                                                                   A.
                                                                         That's correct.
                                                           13
<sup>13</sup> that were exposed to persistent acetaminophen
                                                                   O.
                                                                         And then you're looking at the
<sup>14</sup> exposure which was defined in this study as
                                                              omissions and errors column, and you just
<sup>15</sup> the mother saying that acetaminophen was used
                                                              cited to use the 1.56 from 1.09 to 2.24,
<sup>16</sup> during both interviews, I believe. The score
                                                              correct?
                                                           17
<sup>17</sup> in the right column is a 1.91 from .44 to
                                                                   A.
                                                                         Sorry. That's correct.
<sup>18</sup> 3.38, right?
                                                           18
                                                                         Okay. And the -- that data is
                                                                   0.
19
       A. Could you repeat the question?
                                                              based on 21 children of the 1,300
20
       Q.
             Sure.
                                                              participants, correct?
                                                           21
21
            If you look under males --
                                                                         That is what it says, yes.
                                                           22
<sup>22</sup> well, let's start with all participants.
                                                                         Okay. That's about, what, 1,
                                                                   O.
23
            Do you see that part, where it
                                                              1 and a half percent of the study population?
<sup>24</sup> says "All participants, never sporadic,
                                                           24
                                                                         Approximately.
<sup>25</sup> persistent," Dr. Cabrera?
                                                           25
                                                                         When Dr. Cabrera decided how to
                                                 Page 211
 1
                                                            <sup>1</sup> weigh, quote/unquote, evidence like this, did
        A.
               Yes, I do.
                                                            <sup>2</sup> Dr. Cabrera consider miniscule population
        Q.
               So if you look at any of those
 <sup>3</sup> for all participants, the total score is
                                                            <sup>3</sup> sizes within a larger study to give credit or
 <sup>4</sup> never positive and statistically significant,
                                                              discredit to a result like this?
 <sup>5</sup> correct?
                                                                       I did not discredit the study
                                                            <sup>6</sup> based on a small number of participants. I
               So that's part of the data.
                                                              considered the totality of data.
 <sup>7</sup> There is significant effects in regards to
 <sup>8</sup> omission of errors. The total score is not
                                                                        Okay. And the totality, with
                                                            <sup>9</sup> the total score, for all participants, as we
   significant.
10
                                                              saw above, was not significant, right?
              Okay. And if you look -- then
                                                           11
<sup>11</sup> they break it down by sex, right, between
                                                                        In regard to the CAST total
                                                           12 score, it was still an increased risk at
   male and female children?
13
                                                           13 1.91, but it was not significant based on the
               They do.
14
                                                           <sup>14</sup> confidence interval.
        Q.
               Okay. And if you look at males
<sup>15</sup> with persistent use, it is -- the effect
                                                                        Okay. And that's for males,
<sup>16</sup> is -- the score is 1.91, and it's
                                                           <sup>16</sup> but with all participants, when you consider
<sup>17</sup> significant, correct?
                                                           <sup>17</sup> males and females, it would -- it would be
                                                           <sup>18</sup> even more attenuated, right?
               To be clear, it's 1.91, and the
<sup>19</sup> odds ratio crosses -- crosses 1. So that
                                                           19
                                                                  A.
                                                                        It was.
<sup>20</sup> would not be reported as significant,
                                                                  Q.
                                                                        Okay. And then if we look at
<sup>21</sup> although in the omission errors, the risk is
                                                           <sup>21</sup> females, and we look at -- let's take, for
<sup>22</sup> 1.56 and that is statistically significant.
                                                           <sup>22</sup> example, sporadic use of acetaminophen during
                                                           <sup>23</sup> pregnancy.
<sup>23</sup> It does not cross 1 with the confidence
                                                           24
<sup>24</sup> interval of 1.09 to 2.24.
                                                                       Are you with me --
                                                           25
                                                                        Yes, I am.
        Q. Okay. And that's for 21 of the
```

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Page 214
       O. -- that row?
                                                                      And, in fact, when we look at
            And we look at the total score,
                                                            most of the human data that we have on
 <sup>3</sup> for 287 female children, the score is -- you
                                                            acetaminophen and pregnancy, it was not
 <sup>4</sup> didn't like when I used the word
                                                            collected for that purpose at all, right?
 <sup>5</sup> "protective," so you could use your own. But
                                                                 A.
                                                                        I'm --
 <sup>6</sup> it's protective and statistically
                                                                        Did you say right?
                                                                 O.
 <sup>7</sup> significant, correct?
                                                                        I don't understand the
                                                                 A.
             It was deemed to be
                                                            question.
 <sup>9</sup> statistically significant and with a reduced
                                                                       Okay. Sure. Let me lay a
                                                            little more foundation for you.
11
       Q. Right.
                                                                      You cited and looked at several
12
                                                            ADHD, in particular, but some autism,
            So if we were blindly
<sup>13</sup> practicing medicine and relying only on this
                                                            database studies that looked at pregnancy
14 study and we knew that our patient was going
                                                            databases particularly in Norway and the
<sup>15</sup> to have a girl, this would indicate we should
                                                            Scandinavian countries, correct?
<sup>16</sup> give sporadic dosing of acetaminophen
                                                                       So maybe that's just a
<sup>17</sup> throughout pregnancy to protect from autism,
                                                            difference in definition, but I think of
<sup>18</sup> correct?
                                                            these as -- they're cohort studies.
19
             I would not practice medicine
                                                                        Okay. Cohort studies.
                                                                       Right. Database makes it sound
<sup>20</sup> like that. And I hope no one else does
                                                                 A.
<sup>21</sup> either.
                                                         <sup>21</sup> like their virtual.
22
       O.
             Doctor, based on this study and
                                                                 Q. Okay. Well, there's a dataset
<sup>23</sup> this study alone, in this population, the
                                                         <sup>23</sup> that's based on -- in those countries, it's
<sup>24</sup> mothers who were having girls who took
                                                         <sup>24</sup> based on health registries because of
                                                         <sup>25</sup> national -- you know, public insurance,
<sup>25</sup> acetaminophen actually protected their
 <sup>1</sup> daughters from autism, according to this
                                                            right?
 <sup>2</sup> dataset, correct?
                                                                A.
                                                                       I'm familiar, yeah.
             There was a decreased risk with
                                                                       Okav.
                                                                Q.
                                                                       I've done some work with those
 <sup>4</sup> sporadic use.
                                                                Α.
             And you just said if you could
                                                            studies.
 <sup>6</sup> prescribe medicine, you would not prescribe
                                                                       Okay. So that data was
 <sup>7</sup> acetaminophen based on this one number, and
                                                            collected by the -- by the government of
 <sup>8</sup> that you would agree that applies to any
                                                          <sup>8</sup> those countries not to study acetaminophen,
  number in any study, right?
                                                          9 right?
       A. I wouldn't propose that
                                                                A.
                                                                       Similar to what we do here with
                                                         <sup>11</sup> National Birth Defects Prevention Study,
<sup>11</sup> sporadic use should be used protectively
<sup>12</sup> outside of its use to treat fevers, and in
                                                         <sup>12</sup> which we're also a part of, it's a
<sup>13</sup> which case it very well could provide a
                                                         <sup>13</sup> surveillance. It's to surveil a population
<sup>14</sup> protective effect.
                                                         <sup>14</sup> for adverse outcomes.
                                                                Q. And they run and other
           And you don't -- you don't make
<sup>16</sup> a decision based on one of many findings
                                                         <sup>16</sup> researchers run tons and tons of analysis
<sup>17</sup> statistically in a study, correct?
                                                         <sup>17</sup> across that data because it collects it for
             To be clear, the expectation is
                                                         <sup>18</sup> everybody because it's a national insurance
<sup>19</sup> that none of the findings will be significant
                                                            program, right?
<sup>20</sup> or, if any, that they would only be whatever
                                                         20
                                                                A. I don't know that it collects
<sup>21</sup> the alpha is. So you would expect a false
                                                         <sup>21</sup> it for everyone, but it does collect it for
<sup>22</sup> discovery of, say, 5 percent of that data.
                                                         <sup>22</sup> everyone that's part of the national health
                                                         <sup>23</sup> care system.
            And so we consider all of the
```

24

Right.

²⁴ data under that -- under those understanding.

And it then goes into the ²⁵ system that can be queried in that regard

¹ and -- but the samples themselves are both ¹ was "yes," and then you gave me another ² archived and analyzed because I've been part ² example of clinical studies, right? ³ of the analysis for those samples as well. I -- that was my answer, so... Okay. Fine, then I'll ask it O. Right. My point is, right now someone again. ⁶ could be running comparisons and studies Another example of publication ⁷ across that data for tons of outcomes, and we ⁷ bias is that if you have a study finding a ⁸ will never hear about them because they turn positive association and then a second one out to not be anything, right? comes out, that first author sometimes might A. Well, you're saying if they're do a meta-analysis of the two and republish ¹¹ negative results -- encouraged to also ¹¹ the same thing. ¹² publish the negative results, but I couldn't And they'll get published ¹³ say whether they would or wouldn't publish again, and now it looks like there's three 14 them. studies and a meta-analysis when really it's 15 just still just two studies, correct? Right. But by and large what gets A. Is this a hypothetical? published are -- even if there's negative 17 Q. Yeah. ¹⁸ results with them, it's the positive results If that happened ¹⁹ that people find interesting and that make it hypothetically, then it could create some into the journals most likely, right, most bias in the literature. often I should say? Q. Okay. Let's go back to 22 ²² literature. Most often. I think it's common to like headlines, unfortunately. How important was Exhibit 9 to 24 ²⁴ your causation opinion? 25 A. I'd say it was a study I And there's a name for that, Page 219 Page 221 1 right? considered as part of -- part of the ² analysis, so... A. What is the name for that? ³ Does it say it here? Which number in Table 3 is most Q. Publication bias, right, significant to you for your causation ⁵ Doctor? There's a name you -- people who do opinion? ⁶ this use, and it's called publication bias So my general question is, are ⁷ for what we just discussed? there findings of increased risk in these Ah, in regards to being more tables? And I see that there are increased ⁹ likely to publish positive findings, that risks, particularly with persistent use in ¹⁰ there's potential publication bias there. In omission errors. ¹¹ addition, there's potential publication bias 11 So that would be a finding 12 that's consistent in the different groups in ¹² for repackaging results to pile the ¹³ literature with a particular outcome. omission errors. And we see that sometimes with And how do you balance that ¹⁵ with the lack of findings in several of these ¹⁵ meta-analyses of one or two studies that ¹⁶ really just repeat the same thing, but now 16 results and the opposite findings, the ¹⁷ they're a meta-analysis, right? protective findings? Well, a specific example we see So in regards to the CAST score in particular, it's simply a matter of is -quite often with clinical studies to try to ²⁰ promote the use of particular medications, are we consistently finding negative or ²¹ this packing of the literature, but there is ²¹ decreased risk in multiple studies, if you ²² wanted to say that there was a protective ²² the potential for it in meta-analysis if you ²³ don't consider the same group publishing ²³ effect. We could look for the same thing,

So the answer to my question

²⁴ multiple times.

²⁴ and so to consider that also, so...

Q. Right.

```
Page 222
                                                                                                          Page 224
                                                           1
                                                                     Preceding delivery, okay.
            So if you only had this paper,
 <sup>2</sup> Exhibit 9, would you say that acetaminophen
                                                           2
                                                                      But immediately or close to
                                                           <sup>3</sup> that preceding delivery depending on the
 <sup>3</sup> causes autism in human children?
                                                           <sup>4</sup> half-life of whatever is being studied,
       A. I would say it was still
 <sup>5</sup> unclear.
                                                           <sup>5</sup> right?
 6
            (Cabrera Exhibit 10 marked for
                                                                 A.
                                                                       As a function of the half-life.
       identification.)
                                                                       Okay. And you looked at the
                                                             study already, right?
   QUESTIONS BY MR. MURDICA:
                                                                 A.
                                                                       Yes, I have.
             Let's take a look at another
10 one.
                                                                       Okay. And was the cord blood
11
                                                          <sup>11</sup> in this study collected specifically to study
            Okay. Dr. Cabrera, I've marked
<sup>12</sup> and put in front of you Exhibit 10, and I'm
                                                             acetaminophen?
  going to represent to you that it's a
                                                          13
                                                                 A. Well, initially -- I don't know
<sup>14</sup> Ji study from 2020.
                                                          <sup>14</sup> that they were initially. I'm looking for
15
                                                            that, so...
            Do you have it?
16
                                                          16
             I do, yes.
                                                                 Q.
                                                                       Okay. Do you know how often
17
             Are you familiar with it?
                                                          <sup>17</sup> the mother's exposure to acetaminophen during
       Q.
18
                                                             the pregnancies that resulted in the cord
             Yes, I am.
19
                                                             were collected?
             Do you rely on it in your
       Q.
                                                          20
20
                                                                 A.
                                                                       Could you repeat that question,
  report?
21
       A.
             Yes, I do.
                                                             please?
                                                          22
22
                                                                 0.
             Okay. Now, in Dr. Cabrera's
                                                                       Sure.
       O.
  world, how important are cord blood studies?
                                                          23
                                                                      Ultimately for however many --
24
                                                          <sup>24</sup> so not everyone who was enrolled in this
             It can be very important.
25
             Okay. And where do they fall
                                                          <sup>25</sup> dataset ended up having harvested cord blood,
                                                Page 223
  in your hierarchy of evidence?
                                                             correct?
             If supportive, they provide
       A.
                                                                 A.
                                                                       That is correct.
 <sup>3</sup> strong evidence.
                                                                       Okay. Only about a third
             Okay. And do all cord blood
                                                            actually had their cord blood harvested that
 <sup>5</sup> studies only capture the peripartum period of
                                                           <sup>5</sup> had been enrolled, correct, a little less
 6 time?
                                                            than a third?
             Well, it could be pre or peri
                                                                       To be clear, the math again is
                                                                 Α.
 <sup>8</sup> in regards to cord blood, depending on when
                                                            mother-infant dyads at 3,163, so...
 <sup>9</sup> the medication was administered.
                                                                       You're right. It's more like
                                                             two-thirds, not one-third, fair?
             The cord blood studies that
<sup>11</sup> you're aware of are taken around the time of
                                                          11
                                                                 A. I -- yes, that's -- closer to
                                                          12 two-thirds, yes.
<sup>12</sup> birth, though. This is not like a genetic
13 testing in the first 15 weeks tests we're
                                                                       Okay. And what measurements
<sup>14</sup> talking about, correct?
                                                          <sup>14</sup> were taken throughout the pregnancy as to
                                                          <sup>15</sup> exposures to different medications?
             So the collection of the cord
16
  blood itself is perinatally, during delivery.
                                                                       So the information that they
17
             That's what I was asking you
                                                          <sup>17</sup> include in the study includes maternal age of
<sup>18</sup> originally.
                                                          <sup>18</sup> delivery, maternal race and ethnicity,
                                                          <sup>19</sup> maternal education level, maternal status,
            Okay. So what would be in the
<sup>20</sup> cord blood would reflect -- depending on the
                                                          <sup>20</sup> stress during pregnancy, smoking before or
<sup>21</sup> half-life of whatever we're looking for, it
                                                          <sup>21</sup> during pregnancy, alcohol use before and
<sup>22</sup> would reflect what was in the cord -- or what
                                                          <sup>22</sup> during pregnancy, maternal BMI, parity, child
<sup>23</sup> the cord was exposed to around the time of
                                                          <sup>23</sup> sex, delivery type, preterm birth and low
                                                          <sup>24</sup> birth weight.
<sup>24</sup> delivery, correct?
       A. Preceding delivery.
                                                                      And then there's additional
```

```
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 <sup>1</sup> stratification, but I don't see specific
                                                           <sup>1</sup> that came out of this study, but you know
                                                           <sup>2</sup> that many other things were studied other
 <sup>2</sup> indication about other medication.
                                                             than acetaminophen, right?
             Right.
            Dr. Cabrera, they never asked
                                                                        They did study other things --
 <sup>5</sup> the mothers who -- whose cord blood was
                                                                  Q.
                                                                        Okay.
 <sup>6</sup> sampled here whether they -- whether they
                                                                        -- in this cohort.
                                                                  A.
 <sup>7</sup> took acetaminophen ever once or how often,
                                                                        And you just said, you know,
                                                           <sup>8</sup> it's probably a snapshot of the -- of the
 8 correct?
                                                             half a day before delivery.
       A. I -- my understanding is, as
<sup>10</sup> indicated in my report, they did not ask.
                                                                       They didn't ask the mothers
<sup>11</sup> They measured for acetaminophen in the cord
                                                          <sup>11</sup> whether they took acetaminophen for the
<sup>12</sup> blood but didn't correlate that with a
                                                             initial pains of labor, right?
                                                          13
                                                                  A. As far as I know, there -- they
13 recall.
14
       Q. Right.
                                                          <sup>14</sup> didn't ask the mom about medication usage in
15
            And another way -- so they
                                                             regards to acetaminophen.
<sup>16</sup> didn't ask the mothers if they were exposed
                                                          16
                                                                 Q. And you know that -- well, you
                                                          <sup>17</sup> haven't experienced personally, I assume, but
<sup>17</sup> to acetaminophen. They also didn't ask them
<sup>18</sup> when they were exposed to acetaminophen,
                                                             you know that labor is painful, right?
                                                          19
                                                                  A. I -- I've been told.
   correct?
20
                                                          20
              That is my understanding.
       A.
                                                                  O.
                                                                        You know that one indication
21
             Okay. So the only thing we
                                                             for acetaminophen is pain, right?
<sup>22</sup> have from Exhibit 10 is this one snapshot of
                                                          22
                                                                        I'm aware of that.
                                                                  A.
<sup>23</sup> time right before delivery, correct?
                                                          23
                                                                  Q.
                                                                        Okay. Wouldn't you expect,
             Well, we have acetaminophen
                                                          <sup>24</sup> based on those two facts, that some women
                                                          <sup>25</sup> would have acetaminophen in their cord blood
<sup>25</sup> exposure or documented acetaminophen
                                                Page 227
                                                           <sup>1</sup> because they took acetaminophen shortly
   exposure.
                                                           <sup>2</sup> before they went to the hospital or on their
              Only at this one period, small
 <sup>3</sup> window of time at the very last hour of
                                                           <sup>3</sup> way to the hospital until they got proper
   pregnancy, correct?
                                                             pain management?
                                                                        To be clear, if it was a --
            I disagree with that. It's not
                                                                  A.
 <sup>6</sup> the very last hour --
                                                           <sup>6</sup> that would be something similar to a random
                                                           <sup>7</sup> effect error. You wouldn't expect to find a
              Okay.
       Q.
              -- but preceding pregnancy
                                                             dose-response with an outcome.
 <sup>9</sup> based on the half-life, which is a few hours.
                                                                  Q.
                                                                        Well, I just --
                                                          10
                                                                        Something like a random effect
10
       Q.
              Okay.
11
              And so the expectation is
                                                          <sup>11</sup> error. A random exposure.
        A.
<sup>12</sup> within -- it would be reasonable to say half
                                                          12
                                                                  O.
                                                                        Sure.
                                                          13
   a day of an exposure beforehand.
                                                                       Oh, and we're going to get to
                                                          <sup>14</sup> that. I'm just asking you as a
              Okay. And I asked you before
                                                          <sup>15</sup> logical-thinking, breathing human being who
<sup>15</sup> if this was intentionally -- if this study
<sup>16</sup> was intentionally done to study
                                                          <sup>16</sup> knows a little something about the real
<sup>17</sup> acetaminophen.
                                                          <sup>17</sup> world, would it surprise you if mothers were
                                                          <sup>18</sup> taking acetaminophen for the pains of labor
            Do you now -- do you now agree
<sup>19</sup> that it was just done to study any
                                                          <sup>19</sup> before were properly treated as a -- at a
<sup>20</sup> metabolites in cord blood?
                                                          <sup>20</sup> hospital?
              Based on the study criteria
                                                                  A. If they didn't know the
<sup>22</sup> initially, it was to look at metabolites
                                                          <sup>22</sup> potential risks, then I could understand them
                                                          <sup>23</sup> taking it to help with the pain.
<sup>23</sup> in cord blood.
24
                                                          24
                                                                        And if somebody takes
              Right.
```

So this is -- this is one paper

²⁵ acetaminophen because of the pain of labor on

```
Page 230
                                                                                                       Page 232
 <sup>1</sup> the way to the hospital, what scientifically
                                                           issue, right?
 <sup>2</sup> does that tell you about days in their
                                                               A.
                                                                     Yes.
 <sup>3</sup> pregnancy that they took acetaminophen for
                                                                     Okay. So no developmental
 <sup>4</sup> other reasons?
                                                         <sup>4</sup> issue, only 8.9 percent of them were born
                                                           preterm, right?
             Scientifically you can only
 <sup>6</sup> draw assumptions about their behavior prior
                                                               A.
                                                                     That's what it says, yes.
                                                                     And then for developmental
                                                           issues, for ADHD and ASD in particular, you
       O.
             Right.
 9
                                                           know, one is double, ADHD is double the
            We really know nothing other
  than this one snapshot, right?
                                                           amount of the percentage of preterm birth,
11
             Quantitatively, we don't know
                                                           and ASD is triple, correct?
<sup>12</sup> behaviors prior to that.
                                                        12
                                                                     Approximately.
       Q. Okay. By the way, we're
                                                        13
                                                                     Right.
                                                               O.
                                                        14
<sup>14</sup> talking about cord blood now, but on your --
                                                                    And you'd expect that, wouldn't
<sup>15</sup> on Dr. Cabrera's hierarchy, is a cord blood
                                                           you? Because you know that preterm birth is
<sup>16</sup> study better or less good than a meconium
                                                           one risk of developing ADHD and autism,
<sup>17</sup> study for looking for pregnancy outcomes like
                                                           right?
18 this?
                                                        18
                                                                     There are potentially
19
                                                           neurodevelopmental impacts from a preterm
       A.
             The, I think, meconium study is
                                                        20
<sup>20</sup> better.
                                                           birth.
                                                        21
21
             Okay. All right. Let's get
                                                                     Okay. And in Dr. Cabrera's
  into this a little bit.
                                                           opinion, are those causal, or are those still
23
            On Table 1, which is on journal
                                                           under investigation?
  page 184. Let me know when you're there.
                                                        24
                                                                     In what capacity?
       A. I'm -- Table 1, yes, I'm there.
                                                        25
                                                                     Is preterm birth something that
                                                                                                       Page 233
                                              Page 231
 1
                                                         <sup>1</sup> can be causally associated with ADHD and
       Q.
             Yeah.
            So what this is showing is for
                                                         <sup>2</sup> autism?
 <sup>3</sup> the 998 mothers who had their cord blood
                                                               A. I'd say those are associated.
 <sup>4</sup> taken, this is some of that background
                                                           I don't know that one causes the other.
 <sup>5</sup> information on basically demographics, right?
                                                                     Okay. Is that because you
             Yes. So it's -- Table 1 is
                                                         <sup>6</sup> haven't done a full Dr. Cabrera analysis on
                                                         <sup>7</sup> it yet?
 <sup>7</sup> titled "Maternal and child characteristics
  according to child physician-diagnosed
                                                                     Because as far as I know in the
                                                         <sup>9</sup> literature, there's association, and I
  conditions."
10
                                                           haven't done the analysis either.
       O.
           Right.
                                                        11
                                                                     Okay. And association is not
11
            And for -- let's look at
  something like preterm birth.
                                                        12
                                                           causation, right?
                                                               A. Association in itself is not
            Are you there?
14
       A.
                                                           sufficient for a causation.
             Yes.
                                                        15
             Okay. So the babies who were
                                                                    Okay. Let's look at maternal
<sup>16</sup> born preterm have more than double rate --
                                                           smoking during -- before or during pregnancy.
<sup>17</sup> actually, sorry.
                                                                   Do you see that? It's about
                                                           halfway down the column.
            The babies who were born
  preterm, about 20 percent of them had ADHD
                                                        19
                                                               A.
                                                                     Yes, I do.
  and 28 percent had autism, right?
                                                               Q.
                                                                     Okay. And for a continuous
                                                        <sup>21</sup> smoker, somebody who smoked throughout
             So 28.8 percent had ASD,
                                                        <sup>22</sup> pregnancy, do you see that about 4 percent
  autism, and 20.6 percent had ADHD.
                                                        <sup>23</sup> had no neurodevelopmental issue, 9 percent
             All right. And that's
<sup>24</sup> increased over the first column, right? The
                                                        <sup>24</sup> had ADHD, and 10.6 percent had autism, right?
<sup>25</sup> first column is what? It's no developmental
                                                                    That is correct.
```

Page 234 Page 236 Q. So smokers had a significant I haven't -- I haven't asked, ² increase in ADHD and ASD as a proportion -and so I can't answer that question. ³ as a percentage, right? But that's not defending war There was a significant criminals, right? ⁵ difference in regards to smoking --So Philip Morris isn't in the And -room, so that's -- it depends on who you ask. 7 -- and the outcomes. All right. Let's go on to Table 2. And that's not a surprise to you because you know that ADHD and autism are Let me know when you're there. caused by smoking, right? 10 I'm there. 11 A. I would say that there's --11 Q. Okay. So what Ji did is took ¹² there is an association with smoking and that -- took the acetaminophen metabolite level in the cord blood from that one autism. 14 Okay. So it's the same answer. Q. snapshot in time at delivery, correct? They're analyzing the cord ¹⁵ There's an association, but you don't know ¹⁶ for sure that a mom smoking throughout blood that was collected during delivery. ¹⁷ pregnancy causes autism or ADHD? 17 And in particular, they're Q. 18 A. I haven't personally done a analyzing it for acetaminophen, right? ¹⁹ Bradford Hill on that, but in regards to Acetaminophen and metabolites ²⁰ smoking, smoking has been contraindicated of acetaminophen. 21 during pregnancy as associated with various Right. Right. 22 neurodevelopmental and congenital outcomes. They're using the metabolite as 23 Q. Okay. But you're not ready to a proxy for acetaminophen, right? ²⁴ attribute causation yet, right? Yes. And it's important to Well, I would say it's a risk note the metabolites also have a longer Page 237 Page 235 half-life than just acetaminophen as well. ¹ factor. Q. Okay. It's a risk factor. Okay. How much longer? Are we Q. In Dr. Cabrera's opinion, is talking days? ⁴ acetaminophen more likely to induce autism in A. Days. ⁵ a pregnancy than continuous maternal smoking? Q. Weeks? A. I would say if you wanted to Weeks is probably farther out ⁷ analyze the risk of autism, you should adjust than the metabolites would be expected, but ⁸ for maternal smoking as another risk factor some of them may be within weeks, not longer ⁹ because you wouldn't want to influence the than that. ¹⁰ outcome. O. Okay. And then what Ji did is, 11 ¹¹ depending on the measurement of the cord So independently, I haven't compared them quantitatively with each other. ¹² blood acetaminophen metabolites, broke it Q. But you're going to -- you will ¹³ into three groupings. Basically took ¹⁴ stand up and you will tell the judge in this ¹⁴ every -- all 998 measurements, and not ¹⁵ case that acetaminophen causes autism, but everyone had acetaminophen, right? 16 you won't stand up and say that continuous 16 A. Yes. ¹⁷ smoking during pregnancy causes autism? 17 0. Okay. Took the ones that did, put them all in order, right, from least to A. I would say that there -most or vice versa, and broke it into three 19 they -- you have to modify as -- is it a risk ²⁰ factor for causing ADHD and ASD if you're groups, right? ²¹ analyzing autism. And I'm simply saying I So it's referred to as ²² haven't -- I haven't done, nor have I seen, a tertiles. They've done an analysis and split ²³ Bradford Hill on smoking and autism or ADHD the group into three based on where they fell ²⁴ as an outcome. I'd have to look at that within the group. ²⁵ specifically. Right.

Page 240 But they were even groups. Q. And that alone, even ² Dr. Cabrera would not say that that is ² It's not like there was a threshold for one evidence that you would rely on that ADHD ³ group and a threshold for another. They just ⁴ broke it into three groups, right? ⁴ causes -- or sorry, that acetaminophen causes Well, it's a -- how ⁵ ADHD, correct? ⁶ distributions work, you can just apply a Well, to be clear, that's one Α. ⁷ cutoff, and you end up with thirds based on part of this data. the distribution of a normal distribution. Q. Yeah. Right. A. And so if that was the only 10 part, I would say that it would still be But it wasn't like we're going ¹¹ unclear. But that's -- it's not the only ¹¹ to ignore this group that has -- that has the ¹² low level or anything like that. It was just part. There's also the third tertile where three even groups, right? ¹³ there's -- where the risk continues to go up, 14 ¹⁴ and that's where we see this So the group defines what a low 15 level is. concentration-dependent effect or a ¹⁶ dose-effect with risk. Okay. And it was broken up ¹⁷ into three levels, right? The third tertile 17 O. Yeah. 18 just meant the high -- the grouping of the 18 And so I said that alone, and ¹⁹ highest levels of cord blood acetaminophen you wouldn't rely on that alone. And don't ²⁰ metabolite, right? ²⁰ worry, we're going to go through all of ²¹ these. Yeah. So they're grouping 22 ²² based on the tertiles, and the third group So back to that second tertile ²³ appears to have the highest exposure. ²³ number. The .92, the way statistics works is In terms of the cord blood ²⁴ it could very well be that the actual data ²⁵ measurement, right? ²⁵ there is that the risk effect is .92 below Page 239 Page 241 1 Yes. the null, correct? A. Okay. So the third group had There's a miniscule possibility O. ³ the highest exposure for whatever snapshot in ³ that it could be 0.92 based on the variation ⁴ time the cord blood was able to capture of the point estimate. ⁵ around -- right before delivery, right? Well, these are statistics. So ⁶ define "miniscule." Yes. Okay. And so then if we look A. Well, the distribution is the ⁸ at some measurements, the first tertile, that point estimate of 1.48 is the central ended up being our control, right? tendency. So that's where you would expect A. Yeah, they're giving that a it to be. 11 ¹¹ measure or odds ratio of 1, so that's our --Q. Right. becomes our control. The further you get away from Q. Right. And then so then we ¹³ that, the less is the likelihood that those ¹⁴ look at the second and third tertile. ¹⁴ numbers represent what the point estimate is; that the point estimate is the central And so let's look at, for ¹⁶ example, the first piece of data in here. tendency. ¹⁷ It's ADHD and -- in the second tertile for 17 Q. Right. unchanged acetaminophen. And it very well could be And that is not statistically ¹⁹ there's a -- there's a small possibility that ²⁰ it's 2.39, but there's an equally small ²⁰ significant, correct? A. It's an increased risk, 1.48, possibility that it's 0.92, correct? 22 ²² but it does cross -- it does cross 1. Within the variation, those are 23 23 possibilities.

24

In regards to the confidence

Okay.

A. 25 interval. Okay. And if we look over to

²⁵ the next column, for autism, and unchanged

Page 244 ¹ acetaminophen in the second tertile, we see ¹ but it was -- it could be considered not ² statistically significant. ² something similar, right? 1.32, but not statistically significant, correct? Q. Right. I see 1.33 for the adjusted And, Dr. Cabrera, just to make ⁵ this easier, the plaintiffs' counsel is going odds ratio. ⁶ to have an opportunity to ask you questions Oh, I have a pen mark over Q. ⁷ after I'm done, so you're going to get to mine. So thank you. ⁸ talk about all the things that you think So then if we go down to -- and then there's -- Dr. Cabrera, there's other support your opinion, if I forget to ask you measures for the metabolites, right? about them or choose not to. 11 11 Okay? Yes, there are. 12 12 If you go down to cord And there's data reported for each of those, right? ¹³ acetaminophen burden, you understand that to 14 ¹⁴ be a measure of the unchanged acetaminophen, A. Yes, there are. 15 the glucuronide and the acetyl cysteine So, for example, under glucuronide, one of the metabolites, if there metabolite as well, right? The three that was -- if it was detected -- and it was only ¹⁷ they measured? 18 detected in 192 of them, right? A. The N-acetyl cysteine 19 19 metabolite? Yes. Any detection, 192. 20 20 Q. Q. They didn't break this down Yeah. ²¹ into tertiles because the numbers were too Okay. I'm looking at that. Do 22 low, right? you have a question about it? 23 23 So -- sorry. We're down in the A. Well, because there's -- there ²⁴ was a no detection and any detection, and so ²⁴ last section of rows where it says "cord 25 they broke it down that way. acetaminophen burden"? Page 243 Page 245 Okay. Yeah. So you're --Because only 192 had any ² detection. So they didn't break it up ² okay. We're skipping over N-acetyl cysteine? Yeah. Yeah, my -- I mean, we ³ because the numerosity wasn't high enough, ⁴ can -- we can do it if you want, or you could 4 right? ⁵ do it with your counsel later, but I was just A. Oh, in regards to tertiles? ⁶ going to ask you about the total Q. acetaminophen burden. I can't say the decision on why ⁸ they didn't break it into tertiles other than And my question for you, and I ⁹ the fact that they had a what's referred to ⁹ think we got a little confused there, is the as an unexposed group that was no detection. total cord acetaminophen burden is all of --11 ¹¹ it's the two metabolites they measured plus Okay. And if you look across ¹² to -- they also measured ADHD and ASD pure acetaminophen, right? 13 My understanding, they are together in the same patient, right? 14 ¹⁴ looking at all of the metabolites of They did group them. So in the third column for acetaminophen in that regard. Total burden. ¹⁶ that, when there's some detection of this Okay. And if we look in the ¹⁷ metabolite, it was, again, 1.55 from .053 to ¹⁷ second tertile for autism and autism and ADHD ¹⁸ 4.15, not statistically significant, right? together, we have positive point estimates So to be fair, the adjusted ¹⁹ that are not statistically significant, ²⁰ odds ratio for ADHD was significant with an ²⁰ right? 21 ²¹ increased risk of 2.25. In the second tertile? 22 And the adjusted odds ratio for Q. Yes. For ASD and ADHD with ²³ ASD was also significant for 2.29, but ADHD ²³ ASD. 24 ²⁴ and ASD, the adjusted odds ratio was 1.55, Okay. So just to be clear, the ²⁵ and it did cross 1. Also an increased risk, ²⁵ points there for ADHD, there's a significant

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Page 246
 <sup>1</sup> increased risk for ADHD of 2.26, that's
                                                                        Didn't you wonder what changed,
 <sup>2</sup> significant statistically; an increased risk
                                                            <sup>2</sup> which metabolite -- what was the burden of
 <sup>3</sup> or odds ratio of 2.14, that is not
                                                            <sup>3</sup> the other two metabolites?
 <sup>4</sup> statistically significant; and then for ADHD
                                                                        Inasmuch as we can see that
 <sup>5</sup> and ASD, the odds ratio is 2.1, and it would
                                                            <sup>5</sup> both of the other metabolites showed an
 <sup>6</sup> be considered not statistically significant.
                                                            <sup>6</sup> increased risk when they were detected, or an
              Okay. And in the third
                                                            <sup>7</sup> increased odds ratio when they were detected
                                                            <sup>8</sup> for ADHD, it appears that they were
 <sup>8</sup> tertile, if we look over to ADHD and ASD
<sup>9</sup> together, the point estimate is positive, but
                                                            <sup>9</sup> driving -- that is, those longer-lived
<sup>10</sup> that one is not statistically significant,
                                                             metabolites are -- were driving that
11 correct?
                                                           <sup>11</sup> increased risk.
12
                                                          12
                                                                  Q. On a very -- on a comparatively
        A.
              And, again, for -- to cover all
                                                          <sup>13</sup> small number of patients, right, compared to
13
   of the data --
14
                                                           <sup>14</sup> the unchanged acetaminophen?
        Q.
              Doctor, your counsel --
15
              -- the third tertile --
                                                                        Well, it's still the total
16
              Your counsel's going to --
                                                           <sup>16</sup> number in the second tertile with the cord
17
              -- in the ADHD is 2.86, and
                                                           <sup>17</sup> acetaminophen burden, but it appears to be
        A.
<sup>18</sup> it's statistically significant. For ASD,
                                                              enough to move the odds ratio to an increased
  it's 3.62, and it's statistically
                                                          19
                                                             risk.
<sup>20</sup> significant. But for ADHD and ASD, it is
                                                          20
                                                                        Have you -- have you talked
<sup>21</sup> also an increase odds ratio, but it was not
                                                              to -- do you know Yuelong Ji?
<sup>22</sup> statistically significant. But it was an
                                                                  A. I do not.
                                                          23
<sup>23</sup> increased odds ratio of 2.44.
                                                                  Q.
                                                                        You've never communicated with
              Okay. And, Doctor, when you
                                                          <sup>24</sup> Yuelong Ji?
<sup>25</sup> were looking at this, did you -- were you
                                                                  A. I did not.
                                                                                                            Page 249
                                                           1
 <sup>1</sup> able to figure out the percentage of the cord
                                                                        Okay. So you didn't ask any
 <sup>2</sup> acetaminophen burden that was the metabolites
                                                             questions about this study, I take it?
 <sup>3</sup> versus the unchanged acetaminophen?
                                                                        I have not asked -- I have not
             As far as I know, I didn't see
                                                             been in communication with the authors.
 <sup>5</sup> a -- quantitative values for them.
                                                                        Okay. Did you presume,
             It's not reported, right?
                                                            <sup>6</sup> Dr. Cabrera, that this -- that the
 7
             I haven't seen that data.
                                                              acetaminophen present in the cord blood at
       Q.
             Okay. So you don't know, for
                                                             the time of birth, did you extrapolate that
                                                             in your causation analysis to the entire
  example, for ADHD in the second tertile for
<sup>10</sup> unchanged acetaminophen, it wasn't
                                                              pregnancy of this dataset?
                                                          11
<sup>11</sup> statistically significant, but when
                                                                        To be clear, I took it at face
<sup>12</sup> considering the total burden, it was,
                                                           12 value in that it shows a
<sup>13</sup> correct?
                                                             concentration-dependent or referred to as a
14
                                                           <sup>14</sup> dose-dependent increase in risk.
             Can you repeat the question,
       A.
15
  please?
                                                                  Q. Which could be eliminated,
16
       O.
                                                             corrupted or completely attenuated in the
                                                          <sup>17</sup> circumstance I described where a woman was
17
            For ADHD -- for the outcome of
                                                          <sup>18</sup> taking acetaminophen for the pains of labor,
18
  ADHD --
19
                                                          19 right?
             Okay.
       A.
                                                          20
             -- looking at the second
                                                                        Well, you wouldn't expect that
<sup>21</sup> tertile, for unchanged acetaminophen, there
                                                          <sup>21</sup> to result in an increased risk that was
<sup>22</sup> was no statistically significant effect, but
                                                             dose-responsive in that regard.
                                                                       Moreover, the fact that there's
<sup>23</sup> for total acetaminophen burden for the second
<sup>24</sup> tertile and ADHD, there was, right?
                                                           <sup>24</sup> also increased risks associated with the
```

That is correct.

²⁵ longer-lived half-lives of the other

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Page 250
 <sup>1</sup> metabolites, including the glucuronide and
                                                            <sup>1</sup> have a longer half-life, and those wouldn't
 <sup>2</sup> the N-acetyl cysteine, which is, at least in
                                                            <sup>2</sup> be on the order of hours. It would be days.
 <sup>3</sup> specific cases, would be indicating that it
                                                                         Right.
 <sup>4</sup> interacted with glutathione and that it's
                                                                        And if they -- if the exposure
 <sup>5</sup> actually -- you're detecting acetaminophen
                                                            <sup>5</sup> was days for the longer half-life, it would
                                                            <sup>6</sup> be at a very low dose because days before it
 <sup>6</sup> and glutathione in the newborn's cord blood.
                                                            <sup>7</sup> would be depleting as the half-lives went,
       Q. Did Ji say that in the study?
             I'm familiar enough with the
                                                            8 right?
  biochemistry to understand that.
                                                                         Not necessarily inasmuch as
                                                           <sup>10</sup> there's evidence and -- not yet in humans,
       Q. You've testified before that
11 weeks 2 to 4 of the human pregnancy are the
                                                           <sup>11</sup> but in, I believe, the ewe, which is a --
<sup>12</sup> most sensitive to neurodevelopmental outcomes
                                                             lamb studies, that showed that these
<sup>13</sup> like autism and ADHD.
                                                             metabolites may actually be circulating in
14
                                                           <sup>14</sup> the uterine environment and swallowed and
            Do you recall that?
15
                                                           <sup>15</sup> then recirculated by the -- by the developing
       A. Specifically for neural tube
  defects, those are the sensitive window for
                                                           16 fetus.
                                                           17
<sup>17</sup> neural tube defects.
                                                                        They can actually by and large
18
       Q. Okay. You have no idea for
                                                              accumulate there.
                                                                         That's a -- that's a
   this dataset what acetaminophen, if any, each
   of the 998 mothers took during weeks 2 to 4
                                                           <sup>20</sup> hypothesis, correct, Dr. Cabrera?
   of their pregnancy, correct?
                                                                         That's -- it hasn't been shown
22
       A. Can you clarify what
                                                           <sup>22</sup> in humans, but it has -- it has been shown
  acetaminophen, if any?
                                                           <sup>23</sup> that those metabolites are found in lambs.
24
             Well, yes. I'll rephrase.
                                                                         Okay. Understanding that
                                                           25 they've been found in lambs, Dr. Cabrera,
25
            Dr. Cabrera, for each of the
                                                 Page 251
 <sup>1</sup> 998 women whose cord blood were measured in
                                                              you're not going to testify in front of this
 <sup>2</sup> the study, you don't know if they took
                                                            <sup>2</sup> Court that that's a mechanism of action here
 <sup>3</sup> acetaminophen in weeks 2 to 4 of their
                                                            <sup>3</sup> that you could say with certainty, correct?
 <sup>4</sup> pregnancies at all, correct?
                                                                  A. I can't say that it works just
             I have no way of determining
                                                            <sup>5</sup> like that in humans. There's a study on it
 <sup>6</sup> whether they took medication during the first
                                                            <sup>6</sup> in lambs.
 <sup>7</sup> trimester of pregnancy.
                                                                  O.
                                                                         All right. If you turn to
             You don't know if they were
                                                              page 187 of this, we're under Limitations.
 <sup>9</sup> exposed to acetaminophen during any of the --
                                                                       You see the Ji identified what
<sup>10</sup> of the relevant periods of brain development
                                                              we're just talking about, that a limitation
<sup>11</sup> that even you would testify to, other than
                                                             is that it was only a one-time measurement of
<sup>12</sup> this one day before they gave birth, correct?
                                                              acetaminophen, and it at most reflects
       A. I would say this data is
                                                             maternal use -- may at most reflect maternal
<sup>14</sup> actually most consistent with a third
                                                           <sup>14</sup> use of acetaminophen during the peripartum
<sup>15</sup> trimester exposure. I wouldn't be
                                                           15
                                                              period.
                                                           16
<sup>16</sup> comfortable saying that it included any
                                                                       You agree with that, right?
<sup>17</sup> exposures before that.
                                                           17
                                                                        As I indicated for free
             You only know that they were
                                                              acetaminophen, that's -- that is correct.
<sup>19</sup> exposed one time within six to eight hours
                                                                        Okay. And Ji doesn't say
<sup>20</sup> before the cord blood was taken, right?
                                                              anything else about the metabolites, other
             In regards to the unchanged
                                                              than what I just read to you, right?
                                                           22
<sup>22</sup> acetaminophen, that is the correct
                                                                  A.
                                                                         Not that I've read in the
                                                           <sup>23</sup> study.
<sup>23</sup> assumption.
                                                           24
            In regards to the metabolites,
                                                                         Okay. And one other thing that
```

as I've already indicated, the metabolites

²⁵ Ji says is that liver is the primary location

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Page 254
                                                                                                     Page 256
 <sup>1</sup> for metabolite -- metabolism of
                                                                   MS. KING: How's that?
                                                        2
 <sup>2</sup> acetaminophen.
                                                                   MR. TRACEY: Yeah, that's good.
                                                        3
                                                              It was nothing. Now it's something.
           And you don't disagree with
                                                        4
 4 that, right?
                                                                   MR. MURDICA: I tried. Didn't
                                                        5
            The predominant -- the majority
                                                              work.
 <sup>6</sup> of acetaminophen one consumes would be
                                                        6
                                                          OUESTIONS BY MR. MURDICA:
 <sup>7</sup> metabolized by the liver, which is why
                                                                   All right. Dr. Cabrera, are
 <sup>8</sup> there's increased risk for hepatotoxicity.
                                                          you ready to proceed?
           Okay. And one more question on
                                                              A.
                                                                    Yes, I am.
10 this, and then we can move on.
                                                                    Okay. Earlier this morning
                                                              Q.
11
                                                       <sup>11</sup> when we talked about the various reports
           Yeah, we can take a break.
12
                                                       <sup>12</sup> you've submitted, two of them were your
           Back on page 181, Ji notes in
                                                       <sup>13</sup> original report, and then the amended report
<sup>13</sup> here -- and this is in 2020 he's noting this.
<sup>14</sup> The American Academy of Pediatrics grand
                                                          you submitted a week later.
                                                       15
<sup>15</sup> rounds concluded there's no definitive causal
                                                                   Do you remember those
<sup>16</sup> link between acetaminophen exposure and ADHD.
                                                       16
                                                          questions?
                                                       17
<sup>17</sup> That was in 2020.
                                                              A.
                                                                    Yes, I do.
18
                                                       18
           I take it you disagree now with
                                                                   Okay. And your testimony was
  the American Academy of Pediatrics, right?
                                                          that you made some typographical changes but
19
20
                                                          nothing substantive, right?
            You didn't tell me exactly
  where you're reading that from.
                                                       21
                                                                   That's correct.
                                                       22
      Q. Oh, I apologize, Dr. Cabrera.
                                                                  (Cabrera Exhibits 11 and 12
<sup>23</sup> I use my finger-pointing right here.
                                                       23
                                                              marked for identification.)
24
            Okay. All right.
                                                          QUESTIONS BY MR. MURDICA:
25
            My question to you is, you
                                                              Q. Okay. Marked as Exhibit 11 and
                                                        <sup>1</sup> 12 are your original report and your amended
 <sup>1</sup> disagree with the American Academy of
                                                        <sup>2</sup> report.
 <sup>2</sup> Pediatrics as reported by Dr. Ji here, right?
             I -- inasmuch as this is part
                                                                  Do you have those in front of
                                                          you now, Doctor?
 <sup>4</sup> of the introduction, they're saying prior to
 <sup>5</sup> this study that the American Academy of
                                                              A.
                                                                    Yes, I do.
 <sup>6</sup> Pediatrics grand rounds concluded that there
                                                                    Okay. What I'd like you to do
                                                        <sup>7</sup> is turn to page 135 in the original report,
 <sup>7</sup> was no definitive causal link between
  acetaminophen exposure and ADHD.
                                                        <sup>8</sup> which is the taller stack.
 9
            MR. MURDICA: Okay. We can
10
                                                       10
       take a break. Thank you, Dr. Cabrera.
                                                                    Okay. Let me know when you're
                                                              Q.
                                                       ^{11} there.
11
            VIDEOGRAPHER: Off the record,
12
                                                       12
       2:21.
                                                              A.
                                                                    I'm there.
                                                       13
13
        (Off the record at 2:21 p.m.)
                                                                    Okay. You have a section,
                                                              O.
14
            VIDEOGRAPHER: The time is
                                                          weight of evidence for the APAP, ASD studies?
                                                       15
15
       2:41 p.m. Back on the record,
16
                                                       16
       beginning of Media 5.
                                                              Q.
                                                                    Okay. And then you have a
   QUESTIONS BY MR. MURDICA:
                                                          chart on the next page.
18
                                                       18
             Welcome back, Dr. Cabrera.
                                                              Α.
                                                                    Yes.
19
                                                       19
                                                                   Do you see that?
            Are you ready to proceed?
                                                              O.
20
                                                       20
            Yes, I am.
                                                              A.
                                                                    Yes.
       A.
21
                                                       21
             Okay.
                                                                    Okay. Now, I want you to open
       O.
22
                                                          the amended report to the same section --
            MR. TRACEY: How about sound?
                                                       22
23
                                                       23
                                                              A.
                                                                    Okay.
       I need the sound on.
24
                                                       24
            MR. MURDICA: Oh, I'm muted.
                                                                    -- which I think is -- you got
                                                              Q.
                                                       <sup>25</sup> it?
25
       All right.
```

Page 258 Page 260 A. Yes. Yes, exactly. 2 You weren't cherry-picking data Okay. In the chart on the Q. Q. and realized you didn't like it? amended report, is the Saunders study in 4 there? It wasn't about cherry-picking Α. I do not see it. ⁵ data. It was just that the -- when I was 6 ⁶ formatting the table, that should have been a Q. Is it on the original? I -- yes, it is. ⁷ Liew citation with a hyperkinetic syndrome, A. 8 And in the original, it's in and it ended up being a Saunders. Q. the chart, and then if you look at the text And somehow the word "Saunders" following it, turn -- if you turn the page -just showed up there? 11 11 Oh, yeah. Well, I was reviewing the 12 -- there's a description of ¹² Saunders work as well, and that's how it ended up in the table. ¹³ Saunders as well, right? 14 Yeah, I think it was a -- it So it turns out Saunders is not ¹⁵ was a typo because there's not a description considered in your weight of evidence, of Saunders. correct? 17 17 Q. Okay. Dr. Cabrera, Saunders It was part of my analysis. A. ¹⁸ didn't help you, right? 18 Q. It was? 19 Saunders found no correlation A. Yes. 20 ²⁰ between acetaminophen exposure and autism, But now it's no longer in the O. ²¹ correct? section on weight of evidence? 22 Well, it's two different Well, no longer in that they Α. ²³ questions. Which one do you want me to ²³ didn't have a significant increase in risk in ²⁴ answer? that section. 25 O. Q. So because they didn't have a Okay. How about this? I'll Page 261 Page 259 ¹ start over. ¹ significant increase in risk, it wasn't ² included in your weight of evidence? Saunders found no correlation ³ between acetaminophen exposure in utero and It was part of the weight of A. ⁴ autism, correct? evidence. A. They did not. In regards to that particular ⁶ study, it was referencing the wrong study, Okay. And you had it in your original report, correct? ⁷ and so that's the reason why Saunders was A. Yes, it was. ⁸ removed. And then it is -- it is not in Do you recall any other your current report, correct? substantive changes you made in your amended 11 11 report? A. That's correct. 12 Okay. And you only made That wasn't substantive --13 ¹³ typographical changes in your amended report, MR. TRACEY: Objection to form. ¹⁴ correct? 14 THE WITNESS: It was the fact 15 A. Yes. And to clarify, the that it wasn't referencing the right 16 ¹⁶ information that's listed there with Saunders material too. ¹⁷ is not the correct Saunders information, so QUESTIONS BY MR. MURDICA: ¹⁸ that's why it was removed. That is, the 18 Do you recall changing your ¹⁹ information that follows Saunders is not 19 description of Baker 2020? ²⁰ Saunders information. There -- for the tables, 21 ²¹ there were other editorial typos in the Q. Okay. What is it? 22 I believe that's actually a tables that I had to correct as well. 23 ²³ spillover from Liew. O. Okay. But it included Okay. So Saunders 2019 substance, right? shouldn't have been in there from the start? Well, you know, inasmuch as the

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<sup>1</sup> name was referencing the wrong study or the
                                                          <sup>1</sup> description, right above results, you don't
 <sup>2</sup> study didn't match the reference, those had
                                                          <sup>2</sup> have anything -- or sorry.
 <sup>3</sup> to be corrected. There were, you know,
                                                                     Do you see the limitation
 <sup>4</sup> editorial changes because it -- basically I
                                                            section?
 <sup>5</sup> typed the wrong name there.
                                                                Α.
                                                                      On 138?
             And now I'm asking you about
                                                                O.
                                                                      Yeah, in your original report.
 <sup>7</sup> something different now, Dr. Cabrera. You
   also made changes, additions, substantive
                                                                      Okay. Compare that to your
                                                                Q.
   additions, in your description of the
                                                            amended report.
   meconium study, right?
                                                                      I did add additional
11
                                                         <sup>11</sup> information regarding the meconium.
             I mean, if we want to look at
<sup>12</sup> those particularly, we can discuss them.
                                                                      Okay. So that was -- that was
             I'm asking if you remember.
                                                            not an adjustment to a table, right? That
14
                                                            was a substantive change, Doctor.
            Do you remember that?
15
                                                                      Well, I don't know about
       A. I did make some other changes
   in regards to similar problems with the
                                                            substantive. It was just to define what the
   tables that I had to correct.
                                                            exposure in meconium represents.
                                                                Q. It would also offer as an
             Okay. You don't recall making
19
   any other changes than to two tables?
                                                            opinion about what meconium can capture,
20
                                                         <sup>20</sup> correct?
             I just said I had to make
                                                         21
   similar changes to tables that --
                                                                A. Well, it's more or less by
       Q. Right. Sorry. You know what,
                                                         <sup>22</sup> definition of what meconium has been reported
<sup>23</sup> that was a poor question.
                                                         <sup>23</sup> to capture, but I didn't include a reference
                                                         <sup>24</sup> in that regard. It's just generally
            Other than changes to tables,
                                                         <sup>25</sup> understood.
<sup>25</sup> you don't recall making any other substantive
                                                                                                         Page 265
   changes in your amended report.
                                                                 Q. It's not -- was not -- was not
                                                          <sup>2</sup> a typo and was not fixing a table with a
            Is that fair?
                                                            typo, correct?

    I didn't make substantive

 <sup>4</sup> changes. It was -- these were typos on my
                                                                A.
                                                                       That is correct.
                                                          5
 <sup>5</sup> part where I had referenced the wrong study
                                                                Q.
                                                                       Okay. All right. Let's move
 <sup>6</sup> with the wrong data.
                                                          6
                                                            on.
             Okay. You can put those aside
                                                                      In study design, one thing that
 <sup>8</sup> for now.
                                                          <sup>8</sup> can account for something like genetics,
                                                          <sup>9</sup> which here is -- well, you agree that for ASD
            Oh, you know what, while you
<sup>10</sup> have it, turn to page 136 in the original
                                                         <sup>10</sup> and ADHD, genetics is, even you'd agree, the
                                                         <sup>11</sup> predominant influence on the outcome, right?
<sup>11</sup> report. Where's the current report? This is
<sup>12</sup> the original. Where's the current? This is
                                                         12
                                                                       It depends on the case.
                                                         13
<sup>13</sup> the current?
                                                                       Okay. It has 80 to 90 percent
                                                         <sup>14</sup> inheritability, right, both ASD and ADHD?
            Okay. If you -- in your
<sup>15</sup> description -- in your original report,
                                                                       In twinning studies, there have
<sup>16</sup> Exhibit 11, on page 138, you have a
                                                         <sup>16</sup> been some studies that have reported
                                                         <sup>17</sup> inheritability as high as 80 or 90 percent.
<sup>17</sup> description of Baker, right?
18
                                                                       Okay. One way in a study
       A.
              Yes.
19
                                                            design to account in a situation like this
              Okay. And then in your amended
<sup>20</sup> report, on page 138, you have a description
                                                            where you'd expect a large genetic component
   of Baker.
                                                            is to have sibling controlling, right?
22
            Right?
                                                                      That is a potential study
                                                         <sup>23</sup> design for controlling such things.
23
             Yes.
       Α.
                                                         24
              Okay. Now, if you look at the
                                                                       And one sibling would have been
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third paragraph from the bottom of your

²⁵ exposed to an outcome -- sorry, to an

```
Page 266
                                                                                                          Page 268
 <sup>1</sup> exposure. The other would not have. And you
                                                           <sup>1</sup> an adjusted hazard ratio of 2.77, was
 <sup>2</sup> see if they end up having the same or
                                                          <sup>2</sup> statistically significant.
 <sup>3</sup> different outcomes, right?
                                                                      At the between family level,
             So based on what's referred to
                                                           <sup>4</sup> the -- and adjusted hazard ratio of 1.06,
                                                           <sup>5</sup> which was not statistically significant, the
 <sup>5</sup> as discordant siblings, you can perform an
 <sup>6</sup> analysis that way.
                                                           <sup>6</sup> confidence interval was 0.51 to 2.05 at the
                                                          <sup>7</sup> within family level.
       Q. Yeah.
            And you looked at a study that
                                                                 Q.
                                                                       Right.
  did just that with respect to human beings
                                                                      And you agree that a sibling --
                                                            a sibling -- a controlled study is better
   and ADHD, correct?
11
                                                          <sup>11</sup> than an uncontrolled study, right?
       A.
             I did.
12
                                                                 A. I generally teach the
       O.
             And what's it called?
13
             It was -- I assume you're
                                                            controls -- having controls is important for
                                                            studies.
  referring to the Gustavson study.
                                                         14
                                                         15
15
                                                                       And sibling control in
       O. I am.
16
            MR. MURDICA: We'll take --
                                                             pregnancy outcomes is one manner of control,
17
       we'll mark it as Exhibit 13.
                                                         17 right?
18
                                                         18
            MR. TRACEY: What exhibit
                                                                       That is an approach to doing
19
                                                         19
                                                             these studies.
       number?
20
                                                         20
            MR. MURDICA: 13.
                                                                       Okay. And that result, even to
21
                                                             the authors here, was surprising, right?
            (Cabrera Exhibit 13 marked for
22
       identification.)
                                                                      MR. TRACEY: Object to form.
23
   QUESTIONS BY MR. MURDICA:
                                                         23
                                                                      THE WITNESS: What do you mean
24
                                                         24
             Now, Dr. Cabrera, this dataset,
                                                                 by that result?
<sup>25</sup> the same dataset had previously been examined
                                                                                                          Page 269
 <sup>1</sup> by the same authors and found an association
                                                            QUESTIONS BY MR. MURDICA:
 <sup>2</sup> between ADHD and acetaminophen exposure in
                                                                       Did the -- when sibling control
 <sup>3</sup> the Norwegian health care database, right?
                                                           <sup>3</sup> was applied, even though in Ystrom, it didn't
                                                            attenuate the effect. In Gustavson in the
            Yes, they have.
       Q.
            And this Gustavson study
                                                          <sup>5</sup> same database on the same data with it just
 <sup>6</sup> incorporated a sibling control design like we
                                                            more updated, it did, right?
 <sup>7</sup> just discussed, right?
                                                                      Would you like me to --
       A.
            This study did, as did the
                                                                 A. My reading of this is they
                                                            indicate that these results must be
   previous study.
            And when -- and the previous
                                                            interpreted with caution and need to be
<sup>11</sup> study, you're referring to Ystrom, right?
                                                          <sup>11</sup> replicated in other studies.
       A.
            Yes.
                                                                 Q. And while we're on that topic,
13
       O.
            Okay. And in Gustavson, when
                                                            replication is one of the most important
<sup>14</sup> the sibling control was looked at, the effect
                                                          <sup>14</sup> things you can have when trying to determine
                                                         <sup>15</sup> a causation of an effect to an exposure,
<sup>15</sup> of acetaminophen in correlation with the
<sup>16</sup> outcome of ADHD was completely attenuated or
                                                         16
                                                            correct?
<sup>17</sup> went away in layman's terms, right?
                                                         17
                                                                       Just to clarify, replication
18
            So to be clear, under the --
                                                            is important, yes.
19 long-term exposure was associated with a
                                                                       Okay. Isn't that one of the
                                                                 O.
<sup>20</sup> twofold increased risk of ADHD diagnosis, and
                                                            things you most try to do in order to prove
                                                          21
<sup>21</sup> the adjusted hazard ratio is 2.02,
                                                             an effect?
                                                         22
<sup>22</sup> statistically significant.
                                                                 A.
                                                                       Generally in science you expect
                                                             results to be repeatable.
           In the sibling control model,
                                                         24
<sup>24</sup> the association between long-term
                                                                       Right.
<sup>25</sup> acetaminophen use and ADHD in the child was
                                                         25
                                                                      Okay. And so if you look at
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Page 272 ¹ Table 2 on page 7 of 10 of Exhibit 13, you Well, we know of siblings, ² would see that when you look at acetaminophen ² right -- if you look at a pair of siblings, ³ use of 29 days or more and its correlation ³ or a dyad or triad or whatever you want to ⁴ with ADHD, it was 2.02, and it was ⁴ call it, we know in this study what was ⁵ significant, right? That would be the fourth ⁵ looked at was one that was -- the same ⁶ column over. ⁶ mother, right? This was not an adoption ⁷ study? Model 2 -- you can look at ⁸ model 1 unadjusted or model 2 adjusted. Both (Witness nods head.) ⁹ found a positive correlation or an Q. They both had the same mother, association that was significant, right? correct? 11 11 They're both reporting a You've got to say it for the 12 significant increase -transcript. 13 O. Right. Yes. My understanding is 14 -- in the hazard ratio. they both have the same mother at least. 15 And then if you look at the --One was exposed to ¹⁶ when sibling control was applied in the next ¹⁶ acetaminophen during the pregnancy, and one ¹⁷ column over, regardless of the number of days was not, correct? acetaminophen was used during pregnancy, So to be clear, that's based on the -- there's no effect, and it's not the reporting. Even that is a problem with ²⁰ significant, right? the sib-pair design in that it's more likely When they controlled for family that the exposure would be both, but they're reported as discordant. And that's potential ²² effect, the hazard ratio was 1.06 and was not ²³ significant. grounds for error as well in these studies. 24 Every study that you rely on in Q. And if you look at the two rows ²⁵ above that, for lower durations of use of your analysis, Dr. Cabrera, relies on Page 273 acetaminophen in the pregnancy, it's the reported acetaminophen usage, does it not? ² same, right? There's not a positive effect, That is correct, and that ³ and it's not significant, right? ³ generally biases towards the null. And so the criticism there is actually that that That is correct. ⁵ would bias the study toward the null. In all O. Okay. And that, to a geneticist or somebody who speaks about of those studies as well. genetics like yourself, when you have a Q. According to Dr. Cabrera. complete attenuation of a large -- a According to statistics and A. ⁹ statistically significant effect by applying epidemiology. Q. Everybody who reported ¹⁰ sibling control, that speaks to this being a ¹¹ genetic -- a genetic cause, does it not? ¹¹ acetaminophen usage in the studies was doing so based on memory, correct? It does not specifically speak ¹³ to that. And there's multiple reasons for I mean, could have been an app 14 that. ¹⁴ on their phone. I don't know exactly what To begin with, when adjusting their recollection was based upon. A lot of ¹⁶ for these sibling control, you're only them are referred to as recall. So however adjusting for those factors that are shared. manner of recall that they used to recall ¹⁸ You're not adjusting for those factors that what they had taken previously. may be unshared, and it's one of the Q. And like this study, they generally lump the days together into the ²⁰ weaknesses with these studies. ²¹ number of days' use without regard for Q. Okay. ²² whether it was at day 47 or day 90 of So unshared environmental ²³ pregnancy, right, or later? ²³ factors between the two individuals that are

24

²⁵ missing them.

²⁴ discordant is a problem because you're

A. As far as the exposures go, ²⁵ they lump, you know, 1 through 7 days and 8

¹ through 28 days together and then more than potential problem as well, and inasmuch as in ² their unadjusted model and their adjusted ² 29 days together. Q. And you, Dr. Cabrera, as a ³ model, there's increased risk -- there's ⁴ teratologist, would be much more interested ⁴ cause for concern that they may be ⁵ overadjusting, as I already mentioned, in ⁵ in data that actually identified the days and ⁶ regards to unshared environment variables. ⁶ the lengths of exposure for each particular ⁷ day in pregnancy, correct? Q. Unless Dr. Chung is right and 8 this is a genetic disease, right, The -- I would like -- I would ⁹ Dr. Cabrera? ⁹ like data that showed the particular time ¹⁰ during pregnancy and what's also referred to There's no data to show that as dose and duration as well. And so --¹¹ this is strictly a genetically caused 12 disease. It would be much more -- oh, 13 sorry, go ahead. 13 Okay. Did you rely on any O. 14 ¹⁴ other sibling-controlled studies? And so this is showing duration ¹⁵ but not necessarily the dose during that I did review the previous duration. ¹⁶ Gustavson study, the group that preceded this 17 ¹⁷ one. And most -- if we looked at Q. ¹⁸ every study in your report that evaluated 18 Yeah. It was Brandlistuen. I 19 human data, most of them -- not all of them, said it wrong before. Brandlistuen, not --²⁰ but most of them did just this, right? 20 Yes. And I also reviewed ²¹ Brandlistuen as well. That is to say other studies also reported dose based on duration. Q. Okay. And this could not -- on 23 ²³ the same dataset, this didn't replicate Q. Right. ²⁴ Brandlistuen on sibling control, right? And it would be much more A. Well, to be clear, Brandlistuen ²⁵ illuminating for you as a teratologist to see Page 277 ¹ exactly what the pregnancy was exposed to at ¹ actually looked at different endpoints. And ² the exact morphological time of the embryo, ² so there were some overlapping endpoints, but ³ correct? ³ they also looked at different endpoints. Q. Okay. And Gustavson explains I would say it would be more A. ⁵ informative to have both dose and duration, ⁵ why the outcome was different this time, ⁶ but duration is -- can also be considered a ⁶ right? ⁷ dose in that it's a longer period of They do have some -- they ⁸ exposure. propose some reasons why they may have been ⁹ different, and one of them was also loss of O. Right. But seven days, Dr. Cabrera, if power because it's based on the discordant 11 it was, you know, pregnancy day 3 to 4 and ¹¹ siblings that have the particular outcomes. ¹² then not again for four months for one day And the passage of time and the ¹³ and not again for three months for one day, ¹³ improvement of monitoring and things like ¹⁴ that's not really meaningful to you as a 14 that, right? ¹⁵ teratologist, right? 15 Potentially. A. When the seven -- or one to Okay. Even though you ¹⁷ seven-day exposure occurs would also be ¹⁷ criticize sibling control, regulatory ¹⁸ authorities recognize it as a -- something ¹⁸ informative. ¹⁹ that is positive for trying to find a real 19 Q. Right. Okay. So back to the sibling ²⁰ association versus a non-real association, ²¹ control. You are criticizing the sibling ²¹ correct? ²² control design, but it's better than no A. I don't agree with that. ²³ Typically, it's actually the adoption studies ²³ control, right?

²⁵ and you're biasing towards the null, that's a

Well, if you're overcorrecting

²⁴ that carry the most weight in regards to

²⁵ separating gene environment interactions, not

Page 278 ¹ it's 27 of the document on the bottom. It ¹ sibling-based designs. ² says 27 of 140. They agreed that sibling Yeah, I didn't say which were ³ the best. I said, you are aware that ³ study design to be the most appropriate to ⁴ regulatory bodies recognize sibling-control ⁴ examine such risks in relation to exposure ⁵ as superior to not using sibling-controlled, ⁵ during pregnancy. ⁶ correct? And I take it you dis -- you've just testified you disagree with that, right? A. I'm not aware of that. Q. Okay. And did you find any As I indicated, there is risk adoptive studies that evaluated acetaminophen for biasing towards a null with those study exposure? designs. 11 11 I did not. Okay. You don't have better A. 12 ¹² data that's better controlled than what we Q. Did you read Dr. Chung's 13 report? just looked at in Gustavson, correct? 14 14 A. I have. Is this a quality assessment? 15 I don't have other sib-paired data in that Okay. Did you see her citation Ο. ¹⁶ regard. I think as far as dose effects, we to an adoption study? 17 I -- if I did, I hadn't --¹⁷ can look at Baker and Ji, and they provide very strong data in regards to those types of didn't notice she had a reference to an interactions. adoption study. 20 20 Okay. In your work, Doctor, on Q. Right. ²¹ SSRIs for the plaintiff's Bar, did you 21 But just in a human study like ²² encounter what the European regulatory ²² Gustavson, you don't have better control than ²³ authorities said about the association or ²³ the sibling control present in Gustavson, 24 right? ²⁴ lack thereof between SSRIs and autism? 25 A. I'm not familiar with the If you do, point me to it. Page 279 ¹ European statement on that regard. Well, I think the unmatched control in Gustavson itself speaks for itself Okay. Did you ever render an ³ opinion that SSRIs cause autism? ³ in regards to that it demonstrates that I have not. A. ⁴ there's an increased risk. The application Okay. Did you ever render an ⁵ of the sib-pair, or particularly the O. ⁶ in-family design, as I've already indicated, ⁶ opinion that SSRIs cause ADHD? A. I have not. can bias towards the null, and that's a --8 (Cabrera Exhibit 14 marked for that's a cause for concern. identification.) And your testimony here is that 10 QUESTIONS BY MR. MURDICA: you believe it did bias towards the null, so 11 you do not accept it in your analysis, Q. Doctor, I've marked as ¹² Exhibit 14 a PRAC document. You may not be correct? 13 familiar with what PRAC is, but it's a risk A. Oh, I accept it, but I accept ¹⁴ it with the understanding that that's one of ¹⁴ assessment committee from the European ¹⁵ Regulatory Authority. the risks of doing the sib-pairing design. 16 Okay. That it is your And do you have that in front ¹⁷ of you? ¹⁷ belief -- Dr. Cabrera believes that a 18 sib-pair design has a risk that it biases A. Yes, I do. 19 And I only marked it because towards the null, right? ²⁰ they were looking -- and I know you've opined 20 A. That's correct. ²¹ on SSRIs before. They were looking at And did Dr. Cabrera do any ²² whether SSRIs can cause autism, and they analysis whether that, in fact, happened in ²³ determined that it -- the evidence does not. ²³ Gustavson?

24

But in the context of a drug

²⁵ exposure and autism, they suggest on page --

Simply I went over their data

²⁵ analysis and noticed the design that they've

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¹ of it. ¹ undertaken and what happened when they And you came to the opposite ² applied the model. And so that is a concern ³ with sib-pair design that's understood, conclusion of what Gustavson came to in your ⁴ generally, as in reference to my report as final analysis, correct? ⁵ well. My --6 All right. Did you call on MR. TRACEY: Object to the 7 ⁷ that group at all? Did you contact them in form. 8 Robert, read him the conclusion any way? 9 I have not. of the authors so we can disaviews A. 10 10 Okay. Did you let them know {sic} everybody of what they actually 11 your feelings that what it reflects instead said instead of Murdica's version. 12 is bias? MR. MURDICA: Hey, Sean, if you 13 13 want to testify, I'll put you under Α. I wasn't opining about my ¹⁴ feelings. 14 oath. But you can't tell the witness 15 15 where to go and what to do in the Okay. Well, I mean, if you're ¹⁶ genuinely concerned about what you think is 16 middle of an examination whether 17 ¹⁷ causation, wouldn't you go try to tell you're here or not. I'm sorry, but people, talk to the -- talk to the scientists 18 you can't. 19 who found the opposite? MR. TRACEY: Okay. Then I'll 20 20 If I thought they had an error object to the form. You're 21 ²¹ in the study, then I may reach out to them, misrepresenting what the authors said. 22 ²² if not the editor; more likely the authors And the easiest way to do this is to ²³ first. But it's not that it's an error, I 23 look at what they said. ²⁴ think it's even understood by the people 24 MR. MURDICA: Okay. Thank you, 25 ²⁵ conducting the study that that is a risk. Sean. I appreciate the advice. Send Page 283 1 Okay. You have no specific me a bill. ² facts based on Gustavson to challenge the QUESTIONS BY MR. MURDICA: ³ sibling control. You just have concerns All right. Dr. Cabrera, where ⁴ generally about the methodology and bias, publicly have you ever espoused your view ⁵ right? ⁵ that sibling-control design is not a good way ⁶ to control a study because of the risk of No. Gustavson, I think, ⁷ bias? ⁷ identifies that that's a potential risk in ⁸ the study itself, and I'm happy to find that I haven't performed a sib-pair design myself, and so that's not something I for you. 10 needed to voice publicly. But there's Q. Potential risk, right? 11 11 literature in that, both in the reference Potential risk, yes. A. ¹² literature and in the published literature, Okay. So how did you -- how about limitations, and I reference that in did that factor into your analysis, something ¹⁴ that powerful? Did you write it off? ¹⁴ my report as well. 15 I wrote up the Gustavson study. Q. Okay. 16 ¹⁶ It's in my report. My supplemental report. A. 17 17 You, Dr. Cabrera, haven't You wrote it up, or you wrote O. 18 18 it off? published any such thing, correct? 19 19 Not specifically in that Α. No, I wrote the study up in my 20 regard, I have not published on that. report. 21 21 Okay. Okay. But then you Q. All right. Let's talk a little ²² discredited the findings. bit about dose. I didn't discredit them. I You, Dr. Cabrera, used FDA ²⁴ weighed them based on my understanding of | ²⁴

²⁵ that study design and potential limitations

guidance to calculate an animal equivalent of

²⁵ a human equivalent dose, correct?

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Page 286 Page 288 ¹ not because it's abused or taken with I calculated an animal Α. ² something else? equivalent dose. A. Because even at clinically Q. Right. ⁴ recommended dosages, there's been reports of And I also calculated a human Α. equivalent dose. ⁵ increase in liver enzymes consistent with ⁶ liver damage. Right. 7 And I saw in your rebuttal Q. Dr. Cabrera, regardless of what you think of the approved dose -- and I agree report that you acknowledged, I believe -well, let me ask you this. every regulator in the world disagrees with you, and you're entitled to your opinions, Do you acknowledge that the guidance that you cited was for calculating ¹¹ but I'm entitled to ask about them. an initial safe dose for a first-in-human There is an approved, safe 13 trial -human dose, correct? 14 14 A. That --A. There is a recommended dose. 15 15 Okay. And the guidance that Q. -- where there's only animal you're using is for when there's not a evidence available? 17 ¹⁷ recommended human dose, correct? That is one application of that The title of that document is calculation. 19 in regards to selecting a dose using Well, it's the very title of allometric scaling between an animal and a the document. That's what it says it's for, right? human. 22 22 As I indicated, it is the title O. Okay. So when you already know Α. ²³ the human dose, why not -- why are you still of the document. ²⁴ using the model for calculating a safe dose Okay. And you, Dr. Cabrera, ²⁵ then took, even though there's human data ²⁵ for a first-in-human trial? Page 289 ¹ you reverse-engineered it back to mouse dose Because allometric scaling ² to determine what a safe dose was, right? ² still applies. There's no reverse-engineering. Okay. Is this -- is this FDA ⁴ It's simply math. You can multiply or you ⁴ guidance? Have you used it ever outside the ⁵ can divide, and you can then use the scaling ⁵ context of litigation? A. I mean -- just using as an ⁶ between animals and humans to determine example, this is -- actually, it's not even ⁷ whether it's a human equivalent dose or an ⁸ animal-equivalent dose. open for debate. If you look at the label in the Ofirmev, which I've also referenced, and Right. O. 10 ¹⁰ I think we would all agree that at this time, But in this instance, ¹¹ acetaminophen has been -- we're not doing ¹¹ they understood what a recommended dose was. first-in-human trials, right? ¹² They used the example here in mice of 357 mgs 13 It was not a first-in-human ¹³ per kg per day, 715 mgs per kgs per day, and A. 14 trial. ¹⁴ 1,430 mgs per kgs per day. 15 And then they report that as, We know what a safe human dose 16 ¹⁶ "These doses are approximately 0.43, 0.87 and is, right? 17 ¹⁷ 1.7 times the maximum human daily dose A. That's open for debate. respectively based on a body surface area Okay. Well, for 60-plus years, our regulatory authorities have told us what comparison." 20 ²⁰ a safe human dose is, right? That is allometric scaling. And they apparently got that Q. Okay. Did I ask you about ²² wrong, but that's the reason why it's the that, whatever you're reading? ²³ most frequently caused cases of acute liver 23 That's exactly what you just

Because the dose is wrong and

²⁴ failure.

Okay. Can I have that folder?

asked me about.

Page 290 Page 292 What else do you have over Yes. That is -- this is the ² there? ² standard. As it was written into that label, that is what is used. I've already showed you. This Q. Okay. When have you used this ⁴ is my documents that I've already referenced guidance that we're talking about to ⁵ in my report. calculate a first-in-human dose? O. Okay. I gave you the ones that you A. Well, not a first-in-human don't have. And you have that label. ⁸ dose. I use the table for allometric Okay. So this is -- you're scaling. It's literally posted on my wall at work, and we use it to adjust doses. It's referencing a label for acetaminophen that ¹¹ based on human exposures to convert them to doesn't get processed by the liver? animal dosages. It's a IV acetaminophen. 13 13 Q. Okay. And you don't look at Q. Right. 14 ¹⁴ the recommended -- what do you look at, the A. And part of the utility in that ¹⁵ calculation would also include an injection recommended human dose ---¹⁶ volume, if you wanted to do the calculation 16 Yes. 17 ¹⁷ that way. -- of an approved drug? Q. 18 18 Doctor, you can use whatever A. Yes. 19 tortured method you want. I just got to get Okay. You've never used it in O. ²⁰ the way that the guidance is spelled out; in a record on it. 21 So you just showed me an IV other words, for first-in-human? application, right? We use the allometric scaling ²³ table, which is consistent with the way it's So to be clear, the dosing ²⁴ there is an oral dose that's using allometric ²⁴ used in the literature, which is consistent 25 scaling. ²⁵ with the way it's used in other labels, if Page 291 Page 293 The label is for an IV drug. you go and you look through the literature. ² The maximum recommended human dose is based Even for the acetaminophen ³ on oral exposure, and the data that they're ³ label, they're using allometric scaling to ⁴ studying is at animal oral exposure --⁴ determine the maximum human daily dose and Q. I --⁵ then convert that to an animal equivalent ⁶ dose. -- based on a NTP guideline ⁷ study. O. And you saw that all of our --I agree it's based on oral ⁸ all of the defense experts criticized your --Q. ⁹ the way you calculated the animal dose and exposure. said that you're essentially giving them IV medication does not first 11 get processed through the small intestine and ¹¹ toxic doses, right? You just disagree? ¹² absorbed into the liver -- absorbed through Well, they suggested that ¹³ the small intestine and processed first in applying a safety factor would be required ¹⁴ for just the allometric scaling, and you ¹⁴ the liver, correct? Yes, that is correct. don't need an allometric scaling. 16 Okay. The whole idea to find a Q. 17 That had nothing to do with ¹⁷ safe-in-human dose would be if you've already 18 allometric scaling. tested in animals and you know the NOAEL, Have -- do you know of -- my then you could then calculate a human dose, ²⁰ original question was whether, outside of the ²⁰ apply tenfold less. That's your tenfold ²¹ context of litigation, you've used this FDA ²¹ safety factor, and then apply that for ²² guidance to calculate either a human dose or ²² first-in-human studies. ²³ an animal dose. And I don't think -- I don't That's how that safety factor ²⁴ think you answered that. ²⁴ applies. That's not specific to the ²⁵ allometric scaling, which is based on mixed What's your answer?

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                                                            groups including sulfhydryl groups of
 <sup>1</sup> per meter square metabolism differences
 <sup>2</sup> between humans and animals.
                                                           proteins involved in the protection against
                                                            oxidative stress.
           Right.
            So you skipped the safety
                                                                Q. Right.
 <sup>5</sup> factor part, right?
                                                                     And so it goes from the MIE to
             You don't -- you don't -- the
                                                           the key event to the adverse outcome, right?
                                                          <sup>7</sup> That's how you get an adverse outcome
 <sup>7</sup> safety factor part is part of first-in-human
 <sup>8</sup> dosing. The allometric scaling is not only
                                                            pathway, fair?
<sup>9</sup> used there, but it's also used in EPA
                                                                      Well, each one of the key
<sup>10</sup> guidance in regards to power calculations for
                                                           events is indicated by biological
                                                         11 organization, and -- but, yeah, you would --
<sup>11</sup> converting for animal to human dosage.
                                                           you would generally follow the key events
            It's used throughout the
                                                         13 towards an adverse outcome.
<sup>13</sup> literature. It's used throughout labels. If
<sup>14</sup> you pull out any label, you'll see the type
                                                         14
                                                                Q. Right.
                                                         15
  of calculation that I did.
                                                                     And the MIE is what you start
16
       Q. Okay. So you just disagree
                                                            with, right?
with the defense experts' criticism of the
                                                         17
                                                                      In this example, they're
  way you calculated that?
                                                         <sup>18</sup> described here as molecular-initiating
19
       A. I think they're
                                                            events.
                                                         20
<sup>20</sup> misinterpreting.
                                                                       All right. And then
                                                                Q.
                                                         <sup>21</sup> molecular-initiating event here is the
             Okay. Well, you just mentioned
<sup>22</sup> EPA. So let's look at EPA guidance -- or not
                                                         <sup>22</sup> binding of the thiols by methylmercury
                                                         <sup>23</sup> chloride, mercury chloride and acrylamide,
<sup>23</sup> EPA guidance.
                                                         24 right?
            AOP 20, which we were talking
<sup>25</sup> about before, which your counsel now has a
                                                                      Those are three -- three
                                               Page 295
                                                                                                        Page 297
 <sup>1</sup> copy of, is marked as -- I believe it's
                                                          <sup>1</sup> examples of stressors that can initiate these
                                                          <sup>2</sup> events.
 <sup>2</sup> marked as Exhibit 1.
            If you turn to --
                                                                      Right.
                                                                     And it doesn't say
 <sup>4</sup> unfortunately, Doctor, these pages are not
 <sup>5</sup> numbered the way they appear.
                                                          <sup>5</sup> acetaminophen is one of the MIEs here to
                                                          <sup>6</sup> initiate the event with the -- with binding
            So -- well, I have it, but I --
                                                           of thiol, right?
 <sup>7</sup> if you're able to turn to Appendix 1. It's a
 <sup>8</sup> little after that. It's maybe 20 --
                                                                A. It's listed as a stressor later
                                                           in this study.
             There's pages at the top.
       Α.
10
                                                                Q.
                                                                      Not for this MIE, correct?
       Q.
              Okay.
                                                         11
11
                                                                A.
                                                                      It's not -- it's not under this
       A.
              Maybe yours is stapled. Under
  your staple. Under your binder.
                                                         <sup>12</sup> MIE.
13
             Oh, they're on that side.
                                                                      Okay. So if you -- if you now
                                                         <sup>14</sup> turn to the page with the top 42. Now, this
14
            26, Doctor. Okay. You see it
                                                            is -- this is the next step in the cascade.
  says Appendix 1, and it talks about the MIE
                                                         <sup>16</sup> This is the key event, right?
  and KE and AO, right?
17
                                                         17
                                                                      It's oxidative stress. So it's
              Yes.
                                                         <sup>18</sup> a key event in this pathway.
18
       Q.
             Okay. The MIEs are listed
19
                                                                Q. Right.
  first, right?
20
                                                                     First you have the MIE, right?
       A.
             Yes, they are.
                                                         <sup>21</sup> So the thiols were bound. Now, you have the
             And that is the binding of
  essentially glutathione, right?
                                                         <sup>22</sup> key event of oxidative stress, right?
                                                         23
             Well, this is sulfhydryl
                                                                      This is a key event that occurs
                                                         <sup>24</sup> in the pathway.
  groups, so it doesn't necessarily mean
<sup>25</sup> glutathione per se, but it's sulfhydryl
                                                                Q. Okay. Did I say anything wrong
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Page 298 right, in -- on page 42 of the pathway? ¹ in my question? It is not. I'm just clarifying. A. Okay. And there's three Q. But chloroform is? ⁴ stressors listed here. One is acetaminophen, That's correct. one is chloroform, and one is furan, right? Q. And in your report, you have ⁶ lots of drawings of molecules, That's correct. 7 Okay. And do you know how representations of them. Q. Do you know the difference chloroform works? 9 In what capacity? between chloroform and carbon tetrachloride? 10 Q. As a stressor. Not off the top of my head. 11 11 Q. Do you know what chloroform A. I haven't looked into it looks like molecularly? specifically. 13 Okay. Did you look at the I couldn't draw it for you Q. references underlying this key event in the ¹⁴ right now if you asked. AOP? Q. Okay. Do you have a chemistry 16 degree? 16 A. Yes, I did. 17 Q. Okay. And do you remember what A. I have a background in it showed? chemistry. 19 Q. Okay. The things in your A. I'd have to look at them 20 specifically. ²⁰ report that are drawings of molecules, did 21 you copy those from somewhere? (Cabrera Exhibit 15 marked for 22 identification.) A. If I referenced them, then ²³ there would be reference for those studies. **QUESTIONS BY MR. MURDICA:** Let's take a look. This is If the pictorial representation ²⁵ is in the report, you didn't draw those, Exhibit 15. Page 299 Page 301 Doctor, you now have in front right? ² of you Exhibit 15. This, I'll represent to Α. It's likely I'm referencing in ³ you, and I can show you if you need to, is ³ the studies. ⁴ one of the references for this section of the Okay. So if I asked you to Q. ⁵ draw a carbon tetrachloride right now, you ⁵ AOP. couldn't? And it's what's specifically ⁷ referenced for acetaminophen, chloroform and Α. Carbon tetrachloride I could ⁸ furan as stressors, and you can see it's draw. ⁹ listed in the references. Q. Okay. 10 10 Have you seen this before? That's a simple compound. A. 11 11 A. I believe I did see this O. Okay. But chloroform you 12 reference when I was going through the AOP. couldn't? Okay. And do you consider A. I might not get it right. If ¹⁴ ethanol an oxidative stressor? this is a -- I don't study chloroforms, so --15 15 A. It can produce oxidative O. Okay. 16 stress. 16 -- how different it is from A. carbon tetrachloride, I'm not sure. Okay. And when I asked you 18 ¹⁸ before about carbon tetrachloride as an Q. It's very similar. 19 ¹⁹ oxidative stressor, do you remember your A. ²⁰ answer? 20 It's only one small difference. Q. 21 You had asked me if it was in And that, I'm not sure about. Α. 22 ²² the pathway. I told you I wasn't sure I had Q. Okay. One of the -- one of the ²³ seen that in the pathway previously. 23 chlorines are replaced with hydrogen. 24 Q. I think you said yes, but Okay. I could draw that. A. 25 regardless, it's not -- it's not listed here, Q. Yep. Okay.

Page 302 Page 304 ¹ non-hepatocarcinogens. So in any event, going back to ² Exhibit 15, if you turn to the second page All right. It's not about ³ which has 64 on the top -- sorry, we're back ³ oxidative stress, right? It's about the half-life and the hepatocarcinogenicity? ⁴ on this. Sorry. Oh, we're going back. Well, to be clear, CYP2E1 is an 6 Did I give you the wrong one? Q. oxidation pathway, so it is actually about oxidation, yes. ⁷ It's Jackson. I believe it's 15. What -- which reference are we? O. Right. 9 Q. Jackson. But nowhere in here does it 10 Α. What number? come to the conclusion that acetaminophen is 11 an oxidative stressor in this article, right? Q. 15, I believe. A. Well, by simply saying it is 12 15. Okay. 13 ¹³ oxidized by CYP2E1, it becomes an oxidative Flip the page. Q. 14 ¹⁴ stressor. It's -- that's -- that pathway is A. Yes. 15 called oxidation. It's the second page. 16 I'm going to represent to you Q. And you see in this -- in ¹⁷ that this is -- the only mention of ¹⁷ Figure 2 where it's CYP2E1 ligands, it's acetaminophen in any of the references is ¹⁸ talking about six-hour half-life, right? right here for why it's included as a ¹⁹ That's how it's labeled, 300 milligrams ²⁰ stressor. per kilogram, six hours? 21 21 Do you see in that paragraph it In that example, there's a ²² 12-hour. There's 24-hour, and then there's ²² says low-molecular-weight ligands including ²³ ethanol, acetaminophen, carbon tetrachloride, also a six-hour, and my --²⁴ chloroform, furan, increase CYP2E's --24 Oh, you're looking above? ²⁵ CYP2E1's half-life from 7 to 32 hours? -- understanding is there's Page 303 Page 305 clustering -- that's right. I do see that statement, but it You're looking above. Okay. ² also specifically mentions acetaminophen, Q. ³ particularly in Figure 2, in regards to ³ Okay. ⁴ interactions. So you think on the basis of ⁵ the presence in that figure is why it's All right. Well, I apologize Q. ⁶ listed as a stressor in this adverse outcome ⁶ if I missed that. Figure 2? pathway? The fact that it's metabolized Yes. ⁹ by CYP2E1 and then consumes glutathione in It's listed as APAP multiple 10 the production of NAPQI is why it's listed times. 11 ¹¹ there as being part of an oxidative stressor. Okay. You're looking at the ¹² first and third line? ¹² Quite literally, that pathway of CYP2E1, it's Multiple times. It's listed ¹³ an oxidation pathway. ¹⁴ both under the CYP2E1 ligands based on But, Doctor, this doesn't say clustering analysis, if we're looking at risk ¹⁵ NAPQI anywhere in this article or in this ¹⁶ chart, right? That's your -- that's what you of cancer generation and inflammation. 17 ¹⁷ were saying, separate and apart from this Q. Right. ¹⁸ article, right? And this is listing the ¹⁹ lengthening of the half-life, right? That's CYP2E1 is an oxidation pathway, ²⁰ what this figure is about? ²⁰ so being metabolized by CYP2E1, the process ²¹ is called oxidation. That's why it's part of This looks like it's comparing ²² gene expression that results from these ²² this pathway. ²³ exposures that reflect liver cancer, liver 23 O. Yes. 24 ²⁴ regeneration or CYP2E1 ligand interactions And I just asked you if NAPQI ²⁵ is anywhere in this article. ²⁵ and hepatocarcinogens and

Page 306 That -- that's the product of Otherwise it wouldn't be in the ² fetus. ² the oxidation of acetaminophen is NAPQI. And we'll talk about this In the cord blood? O. ⁴ later, but NAPQI is bound by glutathione if In the -- in the -- yeah, in ⁵ it's produced in the liver, correct? the cord blood of the fetus. Not entirely, but that is the Okay. Just because of its primary antioxidant that normally would mere -- because of its presence, which could have appeared just before the time of absorb. 9 sampling, that's your theory? Q. And in this -- in this --10 It's not a theory. It's there. A. NAPOI. 11 11 Q. In this AOP, the first event Q. Oh, Doctor, I know -- I believe ¹² was binding the thiols, and then you're ¹² that you believe all of the opinions that ¹³ stressing it with acetaminophen or some other nobody else agrees with in the entire world. ¹⁴ I believe you believe them. I'm just trying ¹⁴ stressor as listed here, right? So the thiols are already gone? to get a record. 16 So the -- this stressor as 16 MR. TRACEY: Objection. 17 ¹⁷ listed is oxidation, and so acetaminophen can Argumentative. 18 produce oxidation, and it produces oxidation MR. MURDICA: There's not a 19 ¹⁹ through being oxidized by CYP2E1, so it pending question, Mr. Tracey. ²⁰ itself becomes a stressor. 20 **QUESTIONS BY MR. MURDICA:** 21 In this pathway, the stressor Okay. So the ultimate part of ²² is applied after the first event, which was this pathway is the outcome, and the outcome ²³ the heavy metal, correct? ²³ here is something you attribute to autism, A. If you -- if you wanted to 24 right? ²⁵ start with a mercury exposure, then It's not just a -- what I Page 309 Page 307 ¹ acetaminophen could be a risk factor in ¹ attribute. It's consistent with the OECD ² regards to the outcome for heavy metal ² guidelines as I indicated in my report. Q. Okay. So the outcome of this ³ exposure. What I've done is shown that ⁴ pathway is, in part, autism according to ⁵ Dr. Cabrera, correct? ⁵ acetaminophen is also reducing the amount of ⁶ glutathione, even at clinical levels in A. The -- no. As the pathway ⁷ humans, and that that's an oxidative stressor reads, it's an impairment of learning and ⁸ consistent with the AOP 20. memory in the AOP, but the AOP also offers And you've shown that not in guidance in what that means. 10 your own work, right? And that guidance, which I'll 11 ¹¹ be happy to read into the record, has also I've shown that --12 ¹² been linked to neurodevelopmental diseases You mean in your report? O. 13 -- in this report. and deficits like autism spectrum disorder A. 14 Okay. And you saw the -- every Q. and postnatal motor coordination deficits. ¹⁵ defense expert who works on this stuff Okay. So you would link it to ¹⁶ disagrees with you because they say that autism through this AOP, correct, and you do ¹⁷ there's plenty of glutathione to process the ¹⁷ in your report; is that fair? ¹⁸ maximum recommended dose with a 90 percent 18 A. So those are based on the OECD margin of excess glutathione, right? 19 guidelines. 20 Well, to be clear, we just Do you agree, yes or no? You ²¹ would link this -- you would link this AOP to ²¹ looked at a study, if you recall, and they autism, and you do in your report, correct? ²² had N-acetyl cysteine APAP detected in the ²³ cord blood, and so clearly there's not enough Consistent with the OECD ²⁴ guidelines, I would say that impairments in ²⁴ glutathione to soak up all of the

²⁵ acetaminophen or the NAPQI.

²⁵ learning and in memory in children and animal

Page 310 Page 312 ¹ models and regarding the oxidative stress ¹ plausibility. ² that caused neurodevelopment disorders, the Okay. Are you -- is there some ³ AOP indicates oxidative stress, and I'll ³ reason you can't give a direct answer to my ⁴ quote, "Has also been linked to ⁴ question? Do you find this compelling for ⁵ autism as an outcome in this pathway or not? ⁵ neurodevelopmental diseases and deficits like ⁶ autism spectrum disorder and postnatal As indicated, these -- and I'm ⁷ coordination motor deficits." ⁷ happy to, you know, speak specifically to And you rely on this AOP for ⁸ that. The testing in the animals, they produce core behaviors that are consistent your causation opinion on autism, right? ¹⁰ with what we refer to as autism core So I apply that AOP to see if ¹¹ there's any gaps in the mechanism for ¹¹ behaviors in the animal. So that's part of ¹² understanding whether there's a biological the animal impacts. plausibility. Those parallel to human. And 14 ¹⁴ so there is a parallel there. I'm not Q. Right. 15 And the outcome here is extrapolating. It's just a parallel. Q. Okay. And that parallel is why learning disability, right? 17 Impairment of learning and you used AOP 20 for your causation opinion as to autism, right, among other things? memory. 19 A. Among other things. Q. Impairment of learning and 20 20 MR. MURDICA: Okay. Let's mark memory. 21 21 And you use this outcome and this as 16. 22 extrapolate it to autism and ADHD, correct? (Cabrera Exhibit 16 marked for So to be clear, it's not just 23 identification.) ²⁴ my extrapolation. It's consistent with OECD ²⁴ QUESTIONS BY MR. MURDICA: ²⁵ guidelines on what have also been linked Q. Doctor, did you know that this Page 311 ¹ with these -- with these outcomes. was -- that AOP 20 was rejected with respect ² to autism before its publication? Q. I understand that. But you also -- you you can I have not seen this --4 ⁴ read what you read, but you also --Okay. So --O. ⁵ Dr. Cabrera extrapolates it to autism as well 5 A. -- internal review. ⁶ in your report, right? So this is new to you; that A. I -- the testing that is used, they specifically rejected connecting it to ⁸ some of those also measure the same autism? ⁹ developmental neurotoxicity guideline testing A. I haven't seen this document ¹⁰ that are also -- that are also included in that you've just given me. ¹¹ autism core behaviors and in animals as well. Okay. Do you want to take some 12 time to look at it? Because I'll represent 12 Right. 13 ¹³ to you that AOP 20 originally had an outcome So you took all of that, and ¹⁴ you extrapolated this AOP to autism for your of autism, and it was rejected for lack of ¹⁵ causation opinion, right? 15 validity. 16 A. I used it to see if there MS. KING: Do you have a copy? 17 ¹⁷ was -- to identify whether there was deficits MR. MURDICA: I don't. I only 18 ¹⁸ in the mechanistic cascade as part of have my copy. 19 ¹⁹ biological plausibility for my causality THE WITNESS: Do you want to go ²⁰ analysis. 20 off the record? We can make copies 21 And you found this compelling and --22 ²² for your causality analysis for autism, MR. TRACEY: Yeah, make a copy 23 ²³ correct? of it and read it, Robert. And 24 A. I found that there weren't gaps somebody send me a copy. 25 ²⁵ in the data in regards to a biological MS. JOHNSTON: No problem.

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Page 314
                                                                                                       Page 316
       Let's go off the record and handle
                                                                    Do you know if that's someone
 2
                                                         <sup>2</sup> in the Canadian government?
       that.
 3
                                                                    It looks like they might be,
            VIDEOGRAPHER: Off the record,
 4
                                                          that canada.ca, or is that -- yes.
       3:40.
 5
       (Off the record at 3:40 p.m.)
                                                                    It may -- it may be
 6
                                                           governmental, right, Doctor?
            VIDEOGRAPHER: The time is
 7
                                                               A.
       3:56 p.m., back on the record.
                                                                    Maybe.
 8
                                                                     Okay. And the secondary
       Beginning of Media 6.
                                                               Q.
   QUESTIONS BY MR. MURDICA:
                                                          reviewer, number 1, is someone who appears to
10
                                                        <sup>10</sup> be from some regulatory body in the
             Dr. Cabrera, are you ready to
11
                                                        <sup>11</sup> Netherlands potentially?
  proceed?
12
                                                        12
                                                               A.
                                                                    I'm not sure what rivm is
       A.
             Yes, I am.
13
                                                        13
             Okay. Welcome back.
                                                           related to.
14
            Dr. Cabrera, what's in front of
                                                        14
                                                                     Okay. But the third reviewer,
                                                               Q.
  you is marked Exhibit 16, and before we get
                                                        <sup>15</sup> the secondary reviewer, number 2, you know
  into it, I have some questions for you.
                                                           where that person is from, right?
<sup>17</sup> You -- we've talked a lot about AOPs today.
                                                        17
                                                                     Yes.
                                                               A.
                                                        18
            Have you ever been part of an
                                                               Q.
                                                                    And where is that?
                                                        19
19
   AOP review?
                                                                    Their domain is epa.gov.
20
                                                        20
                                                                     Okay. And I take it you've had
                                                               Q.
       A.
           I have not.
21
             Okay. Have you ever submitted
                                                           a chance to review this document now --
                                                        22
  an AOP yourself for review?
                                                                     Yes. I have.
23
                                                        23
       A. I have not.
                                                                   -- on the break?
                                                        24
             Okay. Is the -- are you
                                                                    Okay. And you understand it to
<sup>25</sup> familiar with the review process that AOPs go
                                                           be the review of AOP 20, correct?
                                                                                                      Page 317
 <sup>1</sup> through?
                                                               A.
                                                                     I do.
       A.
            Yes, I am.
                                                               Q.
                                                                     And this was a prepublication
            Okay. Is it from reading this
                                                           review, right?
 <sup>4</sup> document, or did you know beforehand?
                                                               A.
                                                                     Yes.
            I actually -- there was a
                                                               Q.
                                                                     Okay. And one of the things we
                                                         <sup>6</sup> see is that AOP 20 had been copied from
 <sup>6</sup> presentation on it this year at Birth Defects
 <sup>7</sup> Research Prevention, and I had lunch with the
                                                           another AOP, correct? Based on your review,
 <sup>8</sup> person that had just submitted an AOP, so we
                                                          does that -- what it appears to have been?
 <sup>9</sup> talked about it extensively.
                                                                     It sounds like it was modified
            So in other words, you were at
                                                           from an existing one.
                                                        11
<sup>11</sup> a conference and somebody -- another attendee
                                                               Q.
                                                                     Right.
<sup>12</sup> explained to you the process because they
                                                                    It was essentially copied,
<sup>13</sup> were going through it?
                                                          pasted and then modified, right, with a
                                                        <sup>14</sup> different MIE?
            Well, I was already familiar
<sup>15</sup> with it, but then he also gave me a firsthand
                                                                     Potentially. I didn't get the
<sup>16</sup> account.
                                                          specifics of that in my reading, but it
            Okay. And you see on the first
                                                        <sup>17</sup> sounded like at least part of it was used in
       Q.
  page of Exhibit 16, there are reviewers,
                                                        <sup>18</sup> this AOP.
                                                        19
19
  right?
                                                                     And one of the -- and you
20
                                                        <sup>20</sup> correct me where I'm wrong here, but I'm just
       A.
             Yes.
                                                        <sup>21</sup> trying to make it easier so we can get
            And there's a primary reviewer
                                                        <sup>22</sup> through it.
  and two secondary reviewers, correct?
23
            That's what I see, yes.
                                                                    One of the main points of
24
                                                        <sup>24</sup> feedback from all reviewers is that the
            Okay. And the first one has an
  e-mail extension of @canada.ca.
                                                        <sup>25</sup> outcome in this pathway that's explained
```

Page 318 Page 320 1 ¹ should not be autism, correct? know. A. I think the, you know -- my 2 MR. MURDICA: Okay. You're ³ reading, we can do particular quotes if you 3 defending the deposition in person? ⁴ want, but my reading of it is that if it's 4 MS. KING: Yes. ⁵ going to be autism, they need to state that 5 MR. MURDICA: Okay. Is Sean 6 ⁶ it's autism. If it's going to be as okay? 7 ⁷ endpoints in impairment to learning and MS. KING: It's okay. It's 8 8 memory, then they need to make it impairment okay. I'm sorry to interrupt. I just 9 ⁹ to learning and memory, to pick one. wanted to -- everybody to know if I 10 Q. And they need to have the data start talking, that's why. 11 11 to back it up if they're going to keep autism MR. MURDICA: Okay. All right. 12 ¹² in, correct? We can take a break at any time if 13 13 A. Yeah, there was some necessary, and we're all fine with 14 ¹⁴ conversation in regards to what it would that. 15 15 mean -- what changes would be required if it MS. KING: It's okay. I'm ¹⁶ was autism as opposed to learning and memory. 16 good. 17 And, in fact, the author's **QUESTIONS BY MR. MURDICA:** ¹⁸ response was, quote, "We can totally remove 18 Okay. I believe you would put ¹⁹ the autism aspect and consider only learning them all in the categories of biologic ²⁰ and memory impairment, for which there is plausibility, but you proposed several enough experimental support." mechanisms, I would say, by which 22 Correct? Do you see that? acetaminophen could affect neurologic 23 A. If you're doing a quote, I'm outcomes in your report, right? 24 ²⁴ not sure what page you're on. Let me give you some examples. Q. I wish I could tell you. You proposed that ¹ They're not numbered. I can show you my acetaminophen, as we just talked about with ² copy. It's right there. ² the AOP, could cause oxidative stress via So my question is, the author ³ depletion of glutathione and generation of ⁴ of AOP 20 in response to the feedback on ⁴ excess NAPQI that the glutathione can't process, right? ⁵ removing autism from the three reviewers ⁶ said, quote, "We can totally remove the A. I've seen in studies that ⁷ autism aspect and consider only learning and acetaminophen can lower glutathione levels ⁸ impairment for which there is enough and cause oxidative stress. experimental support." Right. 10 10 Did I read that correctly? And then your theory goes that 11 the oxidative stress can happen not just in 11 That is a correct reading. A. Okay. Did you know before we the liver, it can happen in the fetal brain, ¹³ sat here today that AOP 20 didn't have enough and that stress -- right -- am I with you so ¹⁴ experimental support to include autism as an 14 far? 15 outcome? A. I'm following you. 16 Yep. And you say that, right? I hadn't seen this study prior ¹⁷ The oxidative stress can happen in the fetal ¹⁷ to you showing this internal review. I 18 hadn't seen this internal review. brain, right? 19 19 Okay. All right. We can put A. Yes. ²⁰ that aside. Okay. And then the outcome of 21 ²¹ that from oxidative stress in the fetal brain In your report, you have numerous potential proposed pathways? ²² is some sort of neurological damage, right? 23 MS. KING: I'm sorry, I just 23 Well, it influences the 24 got that text. So I'm taking over ²⁴ behavior of cells by changing the oxidation

now, if that's okay. Just letting you

25

²⁵ in the -- in the cells.

Page 322 endocannabinoid pathway, right? That's one? 1 Q. Right. And the effect on the cells in I did mention, yes, ³ your theory would be the exact right way to endocannabinoids. ⁴ induce ADHD or autism, right? Q. Okay. You gave me a paper ⁵ today that talks about notch signalling and You --6 SOX2, right? (Discussion held off the record.) A. That's correct. **QUESTIONS BY MR. MURDICA:** Are you adding that as a Q. proposed mechanism? I can do that again, if you'd ¹⁰ like. Not currently, other than the 11 ¹¹ fact that they did acetaminophen exposure and A. Please. 12 12 they're looking at particular changes in that Okay. That the proposed ¹³ oxidative stress in the fetal brain can cause ¹³ signalling pathway. So that's a proposed ¹⁴ some sort of neurologic damage that's the ¹⁴ signalling pathway for impacts on the ¹⁵ exact type of cellular damage necessary to ¹⁵ hippocampus, but I'm not -- I haven't started ¹⁶ create the presentation of ADHD or autism, drafting anything about that as a pathway. 17 ¹⁷ correct? Right. 18 18 And I'm just asking you today, So there's a lot there in that regardless of whether you started drafting ¹⁹ interaction inasmuch as changing the redox --²⁰ the redox potential of cells changes their something, are you -- are you going to propose that as a biologically plausible ²¹ behavior. So it can influence the behavior pathway based on the -- on the Xie article ²² of cells during the developing nervous ²³ system, and that can produce adverse outcomes that you handed me today? ²⁴ specific with increased risk of autism --In and of itself, there is some ²⁵ autistic core behaviors. other hippocampal data and impacts, but I --Page 323 that's not something I currently plan to do. 1 Q. Right. Okay. Ultimately, when you And in the section of your ³ report that discusses that mechanism, most of ³ came to your causation conclusion in this ⁴ the endpoints are just neurologic toxicity, ⁴ case, which pathway -- because you proposed ⁵ not autism and ADHD themselves, correct? ⁵ many others, which pathway did you pick? Well, it works through there So the two that I found ⁷ sequentially. So at a molecular level, you ⁷ evidence for when applying the AOP model was ⁸ don't see autism or autistic core behaviors ⁸ the oxidative stress and the endocannabinoid ⁹ neither at a cellular or a tissue level, per pathways. ¹⁰ se. You would only see those at an organism Q. Okay. And the rest of them you ¹¹ level. ¹¹ included as background, essentially? 12 Well, just in regards to there Right. But the pathway that I just are other things that happen -- biological ¹⁴ described is your -- it's your oxidative systems that can interact with those stress proposed pathway to get from ingestion pathways, but those are the core pathways. ¹⁶ of acetaminophen to autism in a human baby, 16 Right. 17 right? 17 The other ones outside of the 18 endocannabinoid and the oxidative stress you A. That is one application, yes. 19 agree are not -- they either don't make it Right. 20 ²⁰ all the way along the pathway or they're not Now, you included, I think, specific to autism or ADHD, correct? ²¹ five or six other potential pathways in your report as well, right? A. So specifically applying the 23 ²³ AOP, there would be gaps in the data that I reference interactions, ²⁴ things that happen in parallel with that. ²⁴ would leave a gap in the biological

Yeah. Antagonism of the

²⁵ plausibility that would need additional data

Page 326 ¹ glutathione and that can increase risk for ¹ to fill in those gaps. So Dr. Cabrera, for his ² oxidative stress. It's been shown in humans, ³ causation opinion, is going on oxidative ³ even in regards to modeling in pregnant mothers. There's NAPQI there. ⁴ stress and endocannabinoid antagonism, right, ⁵ as pathways? And you can look at that Well, I don't know about ⁶ effect. In particular, if you want to look ⁷ antagonism inasmuch as increasing agonist ⁷ at embryos or fetuses, you have to look at ⁸ signal through an anandamide would also be -animal models. But we've seen that there's ⁹ would also be an interaction. So not changes in glutathione in the animal models, ¹⁰ strictly just antagonism because there's also the presence of acetaminophen in those animal ¹¹ some agonism going on there. ¹¹ models, and we've seen the adverse events 12 But that's still an -- the ¹² that are produced in those animal models. 13 ¹³ And those parallel what we see in the endocannabinoid pathway? 14 ¹⁴ literature in regards to epidemiological It's still the endocannabinoid pathway. studies. 16 O. Okay. And now that you've seen 16 So that's a totality of data ¹⁷ that AOP 20 was not intended to be used for ¹⁷ there when we -- when we apply this model to the outcome of autism, are you going to stand those experiments. by your opinions here? Q. Right. 20 So I use the same methodology 20 And the impaired learning that ²¹ as described in -- as I had already ²¹ you get to from AOP 20, because it's a ²² mentioned, the same methodology that was ²² symptom of one of your two outcomes, because ²³ described in AOP, to come to the similar ²³ it's a symptom of autism, you're ²⁴ adverse events, which include impairment of ²⁴ extrapolating it to the -- to the entire ²⁵ learning and memory, which overlap with core ²⁵ autism population as a possible causal factor autism behaviors. and to ADHD, correct? 2 Q. Right. Well, it's not just impairment Some autistic patients have ³ in learning because we also see some other autistic core behaviors in the animals that ⁴ impairment of learning as a symptom. Some, ⁵ but not all, correct? are exposed to acetaminophen. Okay. And your theory, without That is correct. A. human evidence for legal and ethical reasons, Okay. So you're going to rely ⁸ on a pathway that leads to a symptom for some is that acetaminophen can make it across the autistic patients to apply to ADHD and autism fetal blood-brain barrier in enough quantity to deplete all the glutathione in the fetal ¹⁰ for all patients, correct? 11 Not for all patients. It would ¹¹ brain and generate enough NAPQI in the fetal ¹² have to be -- I mean, if we're talking about ¹² brain to cause oxidative stress and cause ¹³ case-specific, you have to consider both ¹³ neurologic changes during development, ¹⁴ genetic and environment interactions. This ¹⁴ correct? ¹⁵ is simply looking at the biological A. It doesn't need to be a ¹⁶ plausibility of those interactions. complete depletion of glutathione. So that's 17 ¹⁷ not correct. Q. Right. So according to Dr. Cabrera on Okay. Anything else about what ¹⁹ the AOP 20 pathway, it's biologically ¹⁹ I just said wrong? Is there anything else ²⁰ plausible to get to impaired learning, wrong with what I just said? ²¹ correct? Well, just to clarify, it So using the AOP 20 as a doesn't need to be a complete depletion of ²³ framework, we can move from -- and I can walk glutathione. through that. 24 Is glutathione not -- in the

Acetaminophen can reduce

opinion of Dr. Cabrera, not effective at

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Page 330
 <sup>1</sup> finding NAPQI?
                                                          <sup>1</sup> now have in front of you what's been marked
             It is, but it doesn't need to
                                                          <sup>2</sup> as Exhibit 17.
 <sup>3</sup> be a complete depletion in order to change
                                                                     Do you have that?
 <sup>4</sup> the cell behavior of stem cells or neuro stem
                                                                      Yes, I do.
 <sup>5</sup> cells.
                                                                Q.
                                                                      All right. And these are
                                                            documents that you reviewed before, right?
             Is it your testimony that NAPQI
 <sup>7</sup> that's bound with glutathione -- to
                                                                      I've seen them.
   glutathione can still change stem cells?
                                                                      They're on -- they're in your
                                                                Q.
             Changing the reduction
                                                            reliance materials?
                                                                      I believe they are, yes.
   potential in a stem cell population will
                                                                      Okay. And they're -- you can
  change the behavior of the cells as indicated
                                                                Q.
  in my report.
                                                         12 tell from the appearance of the first page,
13
       Q. Okay. Even if -- does that
                                                         <sup>13</sup> can you not, that these are documents
                                                            authored by the United States Food and Drug
<sup>14</sup> apply, according to Dr. Cabrera, even if only
<sup>15</sup> 10 percent of the glutathione is needed to
                                                            Administration?
<sup>16</sup> bind all of the present NAPQI?
                                                         16
                                                                A.
                                                                      Yes.
                                                         17
17
             As has been shown, the --
                                                                Q.
                                                                      Okay. Doctor, you have never
<sup>18</sup> that's not a true statement because there's
                                                            been asked by FDA to weigh in on a drug
<sup>19</sup> already N-acetyl cysteine bound to
                                                            label, have you?
  glutathione found in the cord blood. So it's
                                                         20
                                                                A.
                                                                      I'm not a labeling expert.
                                                         21
<sup>21</sup> not enough in order to bind all of it.
                                                                Q.
                                                                      Okay.
                                                                      I've not been asked.
            So some of it is getting to the
                                                                Α.
<sup>23</sup> fetus, and some of it is being metabolized by
                                                                      Okay. In your report and at
                                                                Q.
<sup>24</sup> glutathione in the fetal compartment.
                                                         <sup>24</sup> your deposition today, you've offered
                                                         <sup>25</sup> opinions about what warnings or what labeling
       Q. So now you're relying today,
 <sup>1</sup> Dr. Cabrera, on the 118 patients in the 2020
                                                            is present on acetaminophen.
 <sup>2</sup> Ji study that had acetyl cysteine metabolite
                                                                     Do you remember saying that?
 <sup>3</sup> in their cord blood to substantiate your
                                                                A. I don't know about
 4 theory?
                                                            specifically, but we did have a conversation
                                                            about that.
              That also supports the
 <sup>6</sup> biological plausibility and the causality.
                                                                      Let me -- let me ask
 <sup>7</sup> It's in totality. You can look at the
                                                            you a question.
 <sup>8</sup> breadth and the depth of the data, and it
                                                                     Are you intending to offer an
 <sup>9</sup> supports this interaction and this causality.
                                                            opinion on what the acetaminophen packaging
       Q. I believe that you believe
                                                            or labeling should say?
                                                         11
<sup>11</sup> that, Dr. Cabrera. I do. I can tell you're
                                                                A.
                                                                      I'm not.
12 earnest.
                                                                      Okay. So the section in your
                                                         <sup>13</sup> report criticizing the labeling, should that
            All right. Let's take a look
<sup>14</sup> at -- one of the things I think you said you
                                                         <sup>14</sup> even be in there?
<sup>15</sup> looked at, Dr. Cabrera, is the documents
                                                                      I didn't -- I didn't know that
                                                         <sup>16</sup> I had a specific criticism of the label. I
<sup>16</sup> produced about FDA's own analysis of this,
17 right?
                                                         <sup>17</sup> would need to see the specific reference
18
                                                         18
                                                            you're referring to.
       A.
              Yes.
19
                                                                Q. Okay. In any event, is it
              I take it you didn't bring it
       Q.
                                                         <sup>20</sup> accurate that you're not here today to offer
<sup>20</sup> with you?
21
                                                         <sup>21</sup> any opinion, expert or otherwise, as to what
             I did not.
22
             (Cabrera Exhibit 17 marked for
                                                         <sup>22</sup> the label should or should not say with
23
                                                         <sup>23</sup> respect to pregnancy with respect to
       identification.)
  QUESTIONS BY MR. MURDICA:
                                                         <sup>24</sup> acetaminophen?
           Okay. Dr. Cabrera, you should
                                                                A. I mean, I have an opinion on
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Page 334
                                                                                                    Page 336
 <sup>1</sup> it, but I'm not a labeling expert, so I
                                                       <sup>1</sup> OUESTIONS BY MR. MURDICA:
 <sup>2</sup> wouldn't be offering my expert opinion on
                                                       2
                                                             Q.
                                                                   Right.
 <sup>3</sup> that.
                                                                  And you don't know one way or
             Okay. And you do know, though,
                                                        <sup>4</sup> the other because you don't know what every
       O.
 <sup>5</sup> what the FDA to date has said about whether
                                                         physician in the country knows or believes or
 <sup>6</sup> or not the label should say anything about
                                                         thinks, right?
 <sup>7</sup> the risk of autism or ASD or any neurologic
                                                              A. I do not know what every
 <sup>8</sup> defect during pregnancy with the use of
                                                         physician in the country knows or believes or
   acetaminophen, right?
                                                         thinks.
                                                       10
            I'm aware that they're planning
                                                             O.
                                                                   And even though you don't
<sup>11</sup> on continuing studying this matter and that
                                                         prescribe medicine, it's a risk-benefit
  it's still open for debate.
                                                         analysis no matter what, right?
13
                                                      13
                                                                   I'm familiar with risk-benefit
       Q. And that they have been looking
  at it for -- since at least 2014, right?
                                                         analysis and, yes, that would apply here.
                                                      15
       A. At least since 2015, in their
                                                                   You know there are women with
<sup>16</sup> report, so I assume it started somewhere
                                                         epilepsy who stay on antiepileptic
17
  before then.
                                                       <sup>17</sup> medications during pregnancy, despite known
18
                                                         risk of birth defects with the medication
       Q.
             Uh-huh.
19
                                                         they may be taking, right?
            And even though they're looking
                                                      20
  at it, they've had opportunities for -- you
                                                                   I'm aware of that.
                                                             A.
<sup>21</sup> know, since that period of time to come out
                                                      21
                                                                   And you don't doubt that that's
  and say that the label should be changed, and
                                                         a better gamble than the woman and the child
<sup>23</sup> that has never happened.
                                                         dying if, for example, in a motor vehicle
           They've stuck by the advice
                                                          accident due to an epileptic seizure, right?
<sup>25</sup> that women should contact their physicians
                                                                  MS. KING: Objection to form.
                                                                                                    Page 337
                                                       1
  before taking any medication, right?
                                                                  THE WITNESS: To be clear,
                                                       2
           MS. KING: Objection. Form.
                                                             the -- I -- I've spoken about this
           THE WITNESS: I think that's
                                                             with treating physicians, and they've
 4
                                                       4
       good advice. That being said,
                                                             indicated they would normally switch
 5
                                                       5
       unfortunately, even in the absence of
                                                             to medications that have not been --
       evidence, it has been widely assumed
                                                             such as away from valproic acid, to
                                                       7
 7
       to be safe during pregnancy.
                                                             switch to medications that have not
   QUESTIONS BY MR. MURDICA:
                                                       8
                                                             been associated with adverse outcomes.
             Right.
                                                                  And then try to stabilize the
                                                      10
10
           And it's up to the physician to
                                                             epilepsy prior to pregnancy would be
                                                      11
<sup>11</sup> advise if a patient follows the current
                                                             the preferable route.
<sup>12</sup> labeling and calls a physician, it's up to
                                                       12
                                                         OUESTIONS BY MR. MURDICA:
<sup>13</sup> the physician to offer his or her
                                                      13
                                                                   Yeah. If they can, but that's
<sup>14</sup> recommendation on whether, for that
                                                       <sup>14</sup> not always a possibility. You know that,
  particular patient in that particular
                                                         right?
                                                      16
<sup>16</sup> circumstance, acetaminophen is an appropriate
                                                             A.
                                                                   I'm aware of that.
  treatment, correct?
                                                             Q.
                                                                   Okay. Back to Exhibit 17, if
18
                                                         you turn to Bates label 158. So you've never
           MS. KING: Objection. Form.
19
                                                         looked at FDA's internal regulatory documents
           THE WITNESS: If it says to
20
                                                       <sup>20</sup> before, I take it, unless it was in the
       contact your physician during
21
       pregnancy, and the physician could
                                                         context of litigation?
22
       make that opinion, but I guess the
                                                      22
                                                                   In the context of litigation, I
23
       concern is whether they're fully
                                                      <sup>23</sup> have.
```

24

informed on making that opinion.

24

25

Okay. And I know you're not

²⁵ going to offer a labeling opinion, but did

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Page 338
                                                                                            Page 340
 <sup>1</sup> you see in your review that revising a label
                                                     yes.
 <sup>2</sup> was something FDA put a red X on when they
                                                   2
                                                               And did you see -- and that's
                                                         O.
 <sup>3</sup> reviewed the data that we're going to -- the
                                                     called nonclinical review, right?
  pregnancy data we're going to review here?
                                                               Well, we generally refer to it
           Had you seen this before today?
                                                     as preclinical.
 6
           MS. KING: Objection. Form.
                                                         O.
                                                              Preclinical?
 7
                                                   7
           THE WITNESS: So my read of
                                                             In their pre -- their
 8
      this document was there was some
                                                     preclinical reviewers came to a conclusion
 9
      questions raised in regards to
                                                     that additional animal data was not likely to
10
      reviewing the label, but I do see the
                                                     be informative.
11
                                                  11
      red X that you've indicated on the
                                                             Did you see that?
12
                                                  12
                                                              MS. KING: Objection. Form.
13
                                                  13
                                                             THE WITNESS: I read some
           MR. WATTS: What's the exhibit
14
                                                  14
      number?
                                                         correspondence where the findings were
15
                                                  15
           MR. MURDICA: It's 17.
                                                         of concern, but in regards to
16
                                                  16
                                                         conclusions, there was, to me, some
  QUESTIONS BY MR. MURDICA:
17
                                                  17
                                                         mixed signals. In the epidemiology,
            Okay. Do you recall reading --
                                                  18
  you know FDA did their own epidemiologic
                                                         they needed some more mechanism data
                                                  19
  analysis with their own science -- scientists
                                                         which can be found in the animal
                                                  20
  at various points in '14, '15, '18, '20 and
                                                         models.
                                                  21
  '22, right?
                                                              And in the animal models, they
                                                  22
22
           MS. KING: Objection. Form.
                                                         wanted more specific information on
23
                                                  23
           THE WITNESS: I -- I'm aware
                                                         outcomes, which is found in the human
24
                                                  24
      that they've had ongoing analysis. I
                                                         studies. So you really need to look
25
      have to look specifically in regards
                                                         at those together.
                                          Page 339
                                                                                            Page 341
 1
                                                     QUESTIONS BY MR. MURDICA:
      to the years that you've mentioned.
  QUESTIONS BY MR. MURDICA:
                                                              Dr. Cabrera, the preclinical
                                                   <sup>3</sup> reviewers, what they were really saying is
            Okay. Without reference to the
                                                     that the outcomes in animal models aren't
 <sup>4</sup> years, did you see that they review many of
 <sup>5</sup> the human studies that you reviewed in your
                                                     close enough, predictive enough to ASD and
 <sup>6</sup> report?
                                                   <sup>6</sup> ADHD in humans for further studies to
            They've reviewed some of them,
                                                     elucidate the issue, right?
      Α.
  not all of them.
                                                             MS. KING: Objection. Form.
            Okay. Yeah, I said many.
                                                     QUESTIONS BY MR. MURDICA:
10
           So it depends on when you look,
                                                              Whether you agree with it or
<sup>11</sup> right? The most recent review that we have,
                                                     not, that's what they -- you know that's what
  I believe, is in 2022, so it would be missing
                                                     they said, right?
  whatever came out in the rest of '22 and '23.
                                                  13
                                                             MS. KING: Objection. Form.
14
                                                  14
           Is that what you're referring
                                                             THE WITNESS: Well, if you want
15 to?
                                                  15
                                                         to find a particular quote, we can --
16
                                                  16
                                                         we can look at that, but...
      Α.
            In part, yes.
17
            Okay. Did you compare your
                                                     QUESTIONS BY MR. MURDICA:
                                                  18
  review of the studies to FDA's review of the
                                                               Okay. I'm just asking -- let
  studies before you finalized your report?
                                                  19
                                                     me ask it this way.
            I was already familiar with the
                                                              Do you remember them -- do you
<sup>21</sup> FDA's review of the studies, the past.
                                                  <sup>21</sup> remember that being their rationale for
                                                  <sup>22</sup> saying that additional animal studies are not
            Okay. You know FDA review --
<sup>23</sup> reviewed animal studies about in utero
                                                  <sup>23</sup> likely to be informative?
                                                  24
  acetaminophen exposure, right?
                                                         A.
                                                               For their rationale behind
```

25 that?

I did see some of that as well.

Page 342 1 Q. Yeah. you've got the animal model better than they 2 The applicability, as I do, right? ³ mentioned, because these are animal models, A. I haven't done my own acetaminophen studies in my laboratory. ⁴ whether that was informative on a human ⁵ outcome. Okay. So you just review the existing studies differently than the FDA 6 O. Right. reviewers do, right? Because animal outcomes like we ⁸ were talking about earlier, where you're MS. KING: Objection. Form. 9 ⁹ looking at marbles and socialization and THE WITNESS: I don't -- I 10 everything, the FDA reviewer didn't see those don't know that I review them as being relevant enough to human symptoms in 11 differently inasmuch as I just autism and ADHD, correct? 12 performed a systematic review, but I'm 13 13 considering the totality of data, not MS. KING: Objection. Form. 14 14 THE WITNESS: I can't say. You just siloed data. 15 know, I can't read the person's mind, **QUESTIONS BY MR. MURDICA:** 16 per se, but the -- my takeaway from Okay. In other words, you 17 this information was that there were don't know what FDA reviewed or didn't 18 review; is that what you're saying? some reservations in regards to the 19 19 utility of the animal data for A. Not in total. 20 20 application in the clinical outcomes. Okay. So if you were to -- I Q. ²¹ know you haven't done any studies on 21 The clinical outcomes claim the 22 acetaminophen. same deficiency, that they needed more 23 mechanistic data, which is provided 23 If you were to do one, what 24 ²⁴ would you do in your lab or -- well, you with the animal studies, which really 25 you have to look at that data in total ²⁵ can't do one in your lab. If you were to do Page 343 1 one in a lab, what would you do? to understand what's going on. ² QUESTIONS BY MR. MURDICA: Are you just asking me to design an acetaminophen study? And, Dr. Cabrera, that -- as ⁴ somebody who works on animals every day, that Yeah. Have you thought about it? ⁵ must have jumped out to you, that they didn't 5 ⁶ think any additional animal data would be --I have. A. ⁷ would provide more information, right? Okay. And what would you do? Q. A. It's -- it's not the first time So our normal study design, we A. would -- we would actually follow guidelines. ⁹ I've heard something like that. Q. I take it you disagree since We do guideline studies predominantly in my ¹¹ you work on animals. ¹¹ laboratory, so we would follow study 12 Is that fair? guidelines in regard to animal models and the ¹³ number of animals required. 13 That's a -- I think that's ¹⁴ partially correct inasmuch as we do develop We would do exposures. Our animal models of human disease. We do ¹⁵ exposures, we would include a dose-response ¹⁶ appreciate, as I've already mentioned, ¹⁶ in regards to exposures, typically at the ¹⁷ minimum, two-dose, but typically three ¹⁷ there's differences in species, and that ¹⁸ those are models of human disease. 18 dosages. And I think that inasmuch as we And we would determine changes ²⁰ in maternal weight to make sure there's not ²⁰ can do experiments on them that we couldn't maternal toxicity per se, and then we would ²¹ do on humans, they serve their purpose in ²² look at the weight of the dam throughout ²² that regard.

All right. If it -- I take ²⁴ it -- I may have asked you this before. You

²⁵ haven't attempted to tell FDA that you think

23

0.

²³ pregnancy. We would look at the weight of

And then we would divide them

²⁴ the pups when they're born.

```
Page 346
                                                                                                            Page 348
                                                            <sup>1</sup> "nonclinical data"?
 <sup>1</sup> up beforehand blindly between what their
 <sup>2</sup> exposure was or non-exposure into different
                                                                        Can you give me the Bates
 <sup>3</sup> testing groups, and those would go then
                                                              number on that?
 <sup>4</sup> downstairs into the behavioral testing
                                                                        Sure. It's 147 at the bottom.
                                                            <sup>5</sup> The top of the page, second paragraph.
 <sup>5</sup> facility for analysis.
             And you would give them the
                                                                        Okay.
 <sup>7</sup> same behavioral tests that we talked about
                                                                        So, Dr. Cabrera, you know,
                                                                  O.
   earlier, the three-chamber test, for example?
                                                            <sup>8</sup> because we talked about it earlier and you
              That is one test that we could
                                                            <sup>9</sup> volunteered, that around this time, FDA came
10
                                                           10 out with a statement about ADHD and
   run, yes.
11
                                                           <sup>11</sup> acetaminophen, right?
       Q.
             Okay. You don't have any
<sup>12</sup> additional or special tests compared to
                                                           12
                                                                        Could you repeat the question?
                                                           13
  what's in the literature?
                                                                  O.
                                                                        FDA issued a statement -- a
            I don't know about special. A
                                                           <sup>14</sup> guidance online about ADHD and acetaminophen
15 lot of -- our strength is that it's -- our
                                                              and said they would continue to monitor the
<sup>16</sup> system has largely been automated, so we can
                                                           <sup>16</sup> data, but essentially recommendations on use
<sup>17</sup> do tracking that doesn't require an
                                                           <sup>17</sup> haven't changed?
<sup>18</sup> attendant. You can review the data, but it's
                                                           18
                                                                  A.
                                                                       I'm familiar with that
                                                           19
<sup>19</sup> largely automated to remove any potential
                                                              statement.
<sup>20</sup> bias.
                                                           20
                                                                        Okay. And you see here the
21
            So you're blinded to the
                                                              conclusions that led to it internally, right?
<sup>22</sup> treatment of the animals and the groups, and
                                                              Oh, sorry.
<sup>23</sup> the machines do the -- do the data
                                                           23
                                                                  A. I see specifically the
<sup>24</sup> collection.
                                                           <sup>24</sup> paragraph, their comments in regards to the
                                                           <sup>25</sup> animal studies.
       Q. And the data you collect in
                                                                                                            Page 349
 <sup>1</sup> your hypothetical study would only be as good
                                                                  Q. Right.
 <sup>2</sup> as the model is in terms of measuring those
                                                                       Okay. And this is what I
 <sup>3</sup> behaviors that you associate to human autism
                                                            <sup>3</sup> was -- this is what I relayed to you before,
 <sup>4</sup> and ADHD outcomes, correct?
                                                            <sup>4</sup> right, that behavioral responses in animals
                                                            <sup>5</sup> that are most likely predictive of an ADHD
            MS. KING: Objection. Form.
                                                            <sup>6</sup> response in humans are uncertain and,
            THE WITNESS: If -- I mean, in
 7
       turn, the model is as good as the
                                                            <sup>7</sup> therefore, additional animal studies are not
 8
       model can be, and as a potential
                                                            <sup>8</sup> likely to be informative.
 9
       comparison, we could do a valproic
                                                                       That was their view, right?
10
                                                           10
       acid exposure as a -- as a control in
                                                                        That is a quote in this
11
       addition to treatment with
                                                              document.
       acetaminophen.
                                                                        Okay. And then the next
13
  QUESTIONS BY MR. MURDICA:
                                                              paragraph on March 1st of 2016, whoever was
                                                           <sup>14</sup> doing this review at FDA agreed, the data did
              But even valproic acid doesn't
<sup>15</sup> induce autism or ADHD in every exposure,
                                                              not support a causal association between
                                                              acetaminophen and ADHD at the time, and the
  right?
                                                           <sup>17</sup> TSI would be closed?
17
              It produces autism core
                                                           18
<sup>18</sup> behaviors in a majority of animals, but not
                                                                  Α.
                                                                        I see that as well.
   in every animal.
                                                           19
                                                                  O.
                                                                        Yeah.
                                                           20
                                                                       And you know you disagree with
              If you turn to 147, which is
<sup>21</sup> like the third page in on this, and you look
                                                              that today, but you don't know if you would
                                                              have disagreed with that in 2016, right?
  at the second paragraph down.
23
            Now, this is -- this is talking
                                                           23
                                                                        I do not know.
                                                           24
<sup>24</sup> about 2016.
                                                                        Okay. All right. And then if
                                                           <sup>25</sup> you look down at the bottom of the page,
            Do you see where it says
```

```
<sup>1</sup> there was also human data reviewed, and this
                                                         <sup>1</sup> questionnaires in order to collect the data
 <sup>2</sup> was later. This was a year later.
                                                         <sup>2</sup> based on maternal recall.
           And the reviewers said,
                                                                    And just to reiterate,
 <sup>4</sup> "Although we have more studies, we do not
                                                           generally maternal recall would bias towards
 <sup>5</sup> have higher quality data to better inform
                                                         <sup>5</sup> the null, not away from.
 <sup>6</sup> drug causality, and with these findings being
                                                                     Well, that's -- I understand
 <sup>7</sup> in clinical practice, all of these studies
                                                           you're saying that generally, but in the case
 <sup>8</sup> had significant limitations, uncertainty and
                                                           of surveying for mothers for children with
 <sup>9</sup> critical missing information that precludes
                                                           neurodevelopmental issues, you know it's the
                                                           opposite, right? The -- there is a bias for
  reliable inference of drug attribution."
11
                                                        11 responders for children that actually have
            Do you see that?
12
                                                        <sup>12</sup> the condition, right?
       A. So I -- just to be fair, the
<sup>13</sup> statement begins with "We acknowledge the
                                                        13
                                                                     Well, if -- that would assume
<sup>14</sup> consistency of findings of positive
                                                        <sup>14</sup> that they were developing a bias based on
                                                        15 they're not sure what they're supposed to be
<sup>15</sup> association between APAP and adverse
<sup>16</sup> neurodevelopmental outcomes in the majority
                                                          recalling in regards to that bias.
<sup>17</sup> of published observational studies reviewed
                                                        17
                                                                     Well, did you see, Dr. Cabrera,
18 to date."
                                                           that in some of the studies -- some of the
                                                           surveys, the questionnaires, large
            And then it follows, "Although
                                                           percentages of the respondents were lost to
<sup>20</sup> we have more studies, we do not have higher
<sup>21</sup> quality data to better inform drug causality
                                                          follow-up over the years because some of
<sup>22</sup> and what these findings mean in clinical
                                                          these went to, you know, age 7 of the
<sup>23</sup> studies. All of these studied has
                                                           children, right?
                                                        24
<sup>24</sup> significant limitations, uncertainties and
                                                                     That does happen.
                                                        25
<sup>25</sup> critical missing information that precede --
                                                                     Right.
                                              Page 351
                                                                                                       Page 353
 <sup>1</sup> preclude reliable inference of drug
                                                                     And it happened in the studies.
 <sup>2</sup> attribution."
                                                           You saw that, right?
                                                               A.
                                                                      It does happen.
                                                         4
            And you're familiar with the
                                                               Q.
                                                                      Yeah.
 <sup>5</sup> ADHD studies that existed as of February
                                                                     And the people who were still
                                                           responding at year 7 are biased towards
 <sup>6</sup> 2017, right?
       A. I've reviewed them.
                                                           mothers who are concerned about their
             Yeah.
                                                           children that actually have problems, right?
            And we haven't gone through all
                                                                    MS. KING: Objection. Form.
                                                        10
<sup>10</sup> of them, and it would -- it would take a
                                                                    THE WITNESS: I don't know that
                                                        11
<sup>11</sup> while to do so, and we're not going to do
                                                               that's a bias in that regard, but
                                                               there may be -- and I'd have to look
12 that today.
                                                        12
                                                        13
            But you know that many of them
                                                               specifically at that, whether that
<sup>14</sup> were -- they were data collected essentially
                                                        14
                                                               was -- there was a correlation between
                                                        15
  by surveys, right?
                                                               having an affected child and not being
                                                        16
16
                                                               lost to follow-up.
             Several of them were survey
       A.
                                                                    MR. MURDICA: Okay. Why don't
<sup>17</sup> data.
                                                        17
18
                                                        18
             Yeah.
                                                               we take a break at this point. I need
                                                        19
19
            And they relied on maternal
                                                               about five minutes, just figure out
                                                        20
                                                               what the last bit we're going to do
<sup>20</sup> memory sometimes years after the pregnancy,
                                                        21
21 right?
                                                               is.
                                                        22
             I -- I'm not going to comment
                                                                    Does that work for you, Doctor?
<sup>23</sup> generally on how close temporality --
                                                        23
                                                                    THE WITNESS: I can do that.
<sup>24</sup> temporally they were to when they collected
                                                        24
                                                                     VIDEOGRAPHER: Off the record,
```

25

4:36.

25 the data, but several of the studies did use

Page 354 Page 356 patients taking acetaminophen? (Off the record at 4:36 p.m.) A. I've seen data that supports 2 VIDEOGRAPHER: The time is ³ that. I haven't done a causality analysis in 3 4:56 p.m., back on the record. The ⁴ that regard, but I would say there's data beginning of Media 7. QUESTIONS BY MR. MURDICA: ⁵ that's consistent with causality. But I All right. Dr. Cabrera, are ⁶ haven't performed a causality analysis for ⁷ that. you ready to proceed? Okay. And the data that you've Yes, I am. 9 seen that you say is consistent with Okay. Doctor, we're going to causality relies on induced de novo talk about some things that Dr. Cabrera believes acetaminophen can and cannot cause. mutations, essentially, from acetaminophen as a pathway, correct? Okay? A. It's oxidative damage that can 13 13 Can acetaminophen, in the opinion of Dr. Cabrera, cause neural tube increase the risk of de novo mutations. 15 defects? Right. 16 16 And --A. Only at doses that wouldn't --17 that would be outside the normal intake. A. And chromosome breaks. 18 Okay. So I'm -- that's a good -- and Dr. Cabrera knows that point. I'm going to limit my questions to if that was true, you'd also see solid tumors ²⁰ therapeutic -- normal therapeutic doses in as well as blood cancers, correct? ²¹ line with the labeling. Not necessarily, as solid For a normal therapeutic dose, tumors weren't found in the animal models, ²³ does Dr. Cabrera believe that acetaminophen nor have I seen reports in humans for solid ²⁴ causes major congenital malformations in tumors in that regard. ²⁵ human beings? Q. Okay. Page 355 Page 357 A. I've only seen one study that And I'll add that it, ² would support that in regards to the National oftentimes, particularly may affect highly ³ Birth Defects Prevention Study, and that proliferative cells. And that may be why ⁴ wouldn't be enough data to draw that ⁴ it's leukemias as opposed to other solid ⁵ conclusion. ⁵ tumors. Okay. Does Dr. Cabrera believe In any event, as of today, ⁷ that acetaminophen at a therapeutic dose can Dr. Cabrera hasn't seen enough to say and put cause trisomy in an offspring? ⁸ out for the world that you believe ⁹ acetaminophen in therapeutic doses causes I haven't seen any data that blood cancers, do you? 10 would support that it would cause a trisomy. 11 Okay. Does Dr. Cabrera believe 11 I haven't conducted a causality ¹² that acetaminophen at a therapeutic dose in ¹² analysis on that, so I would not be willing to make that opinion. any human, not just during pregnancy, can Okay. What confounders should ¹⁴ cause hard cancers? 15 ¹⁵ we be accounting for in assessing causality Solid tumors, is that --A. 16 ¹⁶ between acetaminophen exposure and the Solid tumors. Q. 17 I've only seen data, as I've ¹⁷ pregnancy outcomes of discussion ASD and 18 ADHD? indicated in my report, consistent with 19 leukemias, not solid tumors. So to be clear, our animal ²⁰ models remove those confounders. That's one Okay. So the answer on solid ²¹ of the strengths of them. And so we don't tumors would be no, right? ²² have to worry about environmental or genetic A. Correct.

Has Dr. Cabrera seen enough ²⁴ data to say that acetaminophen at therapeutic

²⁵ doses can cause and does cause leukemia in

23

²³ confounders in our animal models. But I can

²⁴ also speak specifically in regards to human

²⁵ studies as well, if you'd like.

Page 358

14

Q. Yeah, let's talk about human ² studies.

What confounders should be ⁴ taken into account?

So some of the things that have ⁶ also been determined as risk factors, and ⁷ we've talked about earlier, so potentially ⁸ smoking or the use of other medications. And ⁹ that would include things like valproic acid, ¹⁰ exposures to heavy metals, whether those are ¹¹ environmental or occupational exposures.

And as a more general 13 statement, you need to consider -- those are ¹⁴ just known risk factors in that regard. You ¹⁵ need to consider all the various factors in ¹⁶ order to do a weighted analysis for that.

- 17 How about maternal or paternal Q. ¹⁸ ADHD?
- A. You have to consider this as a potential risk in that there may be some genetic liability as well if there's maternal ²² or paternal ADHD or ASD, even, for that ²³ matter, present on the mother or father. ²⁴ It's a potential genetic component.

O. Particularly if the offspring

Page 359

¹ ends up with ADHD and the parents or parent ² have ADHD, even Dr. Cabrera would be ³ suspicious of a genetic cause there, right? A. I don't know about "even

- ⁵ Dr. Cabrera," but actually one of the first ⁶ things we do is normally conduct a genetic ⁷ analysis.
- Okay. Because you would be ⁹ suspicious for genetics as a cause there, right?
- 11 A. Well, it's because it's one of ¹² the tools we have in the laboratory. We like ¹³ to apply the tool to see if there is a ¹⁴ genetic cause. It's --

Q. Right.

- 16 -- an open question that we ¹⁷ normally apply upfront.
- And if the parents have the condition, you're not doing it for laughs; you're doing it because you suspect that's a possibility, right?
- Yeah, we do -- typically we do ²³ a trio analysis, and we'll look for rare ²⁴ variance or mutations in the mother or ²⁵ father, or look for de novo mutations as

¹ well. So you could have two rare mutations

² come together in the offspring and that could

³ increase disease risk, or you could have de

- ⁴ novo mutations that could also increase ⁵ disease risk as potential genetic factors.
- Okay. Back to confounding in ⁷ human data that Dr. Cabrera believes we need to account for here.

Is impulsivity in the mother a risk factor?

- 11 I haven't seen specifically 12 impulsivity as a -- as a risk factor for ¹³ autism.
 - How about anxiety? Q.
- 15 I think there's some overlap in ¹⁶ regards to anxiety and autism or ADHD ¹⁷ behaviors, and so there -- that could be a ¹⁸ facet of the presentation that should be 19 considered.
- 20 Okay. So anxiety in the mother ²¹ is something you would consider as potential confounding?
- 23 Something in -- as reviewed --²⁴ if you think about this as a part of the ²⁵ nurturing environment, then you have the

potential for mom and dad to not just provide ² genetics in regards to the offspring, but

- ³ also how they influence the environment; both
- ⁴ the in utero environment and also the
- ⁵ environment that the child would be exposed ⁶ to, you know, afterwards.
- Q. Have you seen data on whether ⁸ anxiety in a mother increases the risk of ADHD or autism in the child?
- A. I've seen analysis on various ¹¹ behavioral interactions. I'd have to look ¹² back specifically for anxiety.
- Q. Okay. Would Dr. Cabrera today ¹⁴ consider that confounding for the outcome of interest or potentially confounding or not?
- A. I think potentially it should ¹⁷ be considered if it -- particularly if it's severe or debilitating.
- And if I asked you that same series of questions for depression in the ²¹ mother, would I get the same answer?
- Well, actually, slightly ²³ different answers. And the question is ²⁴ whether the depression is being treated and ²⁵ with what other medications it could

```
Page 362
                                                                                                         Page 364
 <sup>1</sup> potentially being treated with, and you'd
                                                            rate of anxiety and depression?
 <sup>2</sup> have to be concerned about potential
                                                                      I've seen studies specific to
 <sup>3</sup> exposures to those medications as well.
                                                            neuroticism. I'm not sure in regards to
       Q. Okay. How about untreated
                                                            anxiety and depression.
                                                                      Okay. You didn't have any
 <sup>5</sup> depression, potentially confounding or no?
            It depends on the severity and
                                                            citation in your report to any study like
 <sup>7</sup> whether it's -- has -- oftentimes, I'm sure
                                                            that, right?
 <sup>8</sup> you're aware, there can be risk behaviors
                                                                 A.
                                                                       Initially, no. I did review
 <sup>9</sup> associated with depression. And so you would
                                                            some of the work -- or some of the references
10 need to account for that if there's
                                                            by Dr. Chung in that regard.
                                                         11
<sup>11</sup> particular risks associated with that
                                                                       Okay. Have you ever seen a
<sup>12</sup> depression.
                                                         12 study by Bandoli? Does that sound familiar
13
            Okay. Any other confounders
                                                            to you?
       O.
<sup>14</sup> you can think of other than the ones we
                                                         14
                                                                 A.
                                                                       I need to see the study to let
  discussed?
                                                            you know.
16
                                                         16
             So generally what is also often
                                                                 Q.
       A.
                                                                       Okay. I'm going to mark it and
<sup>17</sup> adjusted for is -- drinking or smoking is
                                                            hand it to you.
                                                         18
  also usually adjusted for in those models as
                                                                      MS. JOHNSTON: 18?
19 well.
                                                         19
                                                                      MR. MURDICA: It's going to be
20
                                                         20
             One quick question, and this
                                                                 18, yeah.
<sup>21</sup> was just something I wasn't sure.
                                                         21
                                                                      (Cabrera Exhibit 18 marked for
                                                         22
            In your report you have a
                                                                 identification.)
  biological gradient section, right?
                                                            QUESTIONS BY MR. MURDICA:
             Okay.
                                                                       Doctor, you now have in front
25
            And it says, "Meta-regression
                                                            of you what's been marked as Exhibit 18.
                                               Page 363
                                                                                                         Page 365
 ^{\scriptsize 1} analyses indicate," and I think there's two
                                                                     Take as long as you need to
 <sup>2</sup> that you were referring to.
                                                          <sup>2</sup> review it. I can tell you that my question
                                                          <sup>3</sup> is going to be on page 5 under the topic --
            Do you happen to know, as you
 <sup>4</sup> sit here today, what you were referring to
                                                          <sup>4</sup> under the section Characteristics of Women By
 <sup>5</sup> there with meta-regression analyses, by any
                                                          <sup>5</sup> Duration of Use.
 <sup>6</sup> chance?
                                                                     Do you want to go off the
                                                            record, Doctor?
       A.
             Could you tell me what page
 8 that's on?
                                                                      I just finished.
                                                                A.
       Q.
             Yeah, it's 191.
                                                                      Oh, okay.
10
             Okay. That was my reference to
                                                                     Okay. Doctor, I know your
11 meta-analysis that was performed at the
                                                         <sup>11</sup> counsel had volunteered that he had reviewed
   meta-analysis that I reviewed.
                                                            this paper before today and knew it by name
13
                                                            and year, but I take it Dr. Cabrera didn't
            Yeah.
14
                                                         14 know about?
            Do you know which one?
15
                                                         15
       A. I reviewed all the ones I could
                                                                A. I had looked over it in regards
16
   find, and they're in my report.
                                                            to some of the interactions.
17
             Oh, okay. So it was the prior
                                                                      Okay. And you see, and I
18
                                                         <sup>18</sup> directed you to the section, that the -- in
   meta-analyses in your report.
19
                                                            this study of the 1,515 women who reported
       A.
             Yes.
20
                                                            prospectively acetaminophen use during
       Q.
            Got it.
            Back to the questions I just
                                                         <sup>21</sup> pregnancy, the ones that had the longest use
                                                         <sup>22</sup> were more likely, among other things, to
<sup>22</sup> asked about depression and anxiety. Are you
<sup>23</sup> aware that there are studies showing that the
                                                         <sup>23</sup> report depression or anxiety, right?
<sup>24</sup> population of acetaminophen users have a much
                                                                      That is consistent with the
```

²⁵ higher rate of -- the moms have a much higher

²⁵ fourth paragraph on page 5.

Page 366 Q. Okay. And is the possibility ¹ that one of the studies that you cited, ² of confounding from the symptoms of ² Richey from this year, determined that there ³ wasn't enough homogeneity among the autism ³ depression and anxiety in long-term users ⁴ during pregnancy something you considered in ⁴ data that's out there in humans to conduct a ⁵ your opinions before you rendered them? meta-analysis? Inasmuch as these are things Are you -- are you referring to ⁷ that could be influencing the population. the -- the heterogeneity analysis in Richey? ⁸ They would also -- with the expectation that Q. Yes. ⁹ a particular exposure to a -- to A. I am familiar with that Richey ¹⁰ acetaminophen could have some correlations analysis in regard to the -- they refer to as ¹¹ with depression, anxiety or mental health. a heterogeneity analysis. ¹² I'm not aware that depression, anxiety or 12 Okay. Q. 13 ¹³ mental health themselves can cause the Typically indicated as an ¹⁴ condition of ADHD or ASD in the offspring. ¹⁴ I-squared value. 15 Notwithstanding that, Right. ¹⁶ Dr. Cabrera, in this study, at least, 16 The data wasn't similar enough ¹⁷ long-term users were different than other ¹⁷ to put it all together in a meta-analysis in ¹⁸ users in terms of their weight, their tobacco plain language, correct? 19 use, their use of antidepressants in There was -- there was -- and I ²⁰ pregnancy and their depression and anxiety, ²⁰ don't know about it wasn't similar enough, 21 right? but there was -- the studies have been 22 Right. So, well, weight, it conducted in different ways to create some ²³ should be adjusted for. And as I already ²³ difficulties in that regard. ²⁴ mentioned, potentially alcohol or smoking 24 Right. ²⁵ should be adjusted for. And you don't deny that Richey, Page 369 Page 367 ¹ at least, determined that it wasn't possible And the studies you looked at ² to do a meta-analysis on the existing human ² didn't adjust for depression or anxiety, ³ correct? ³ data with autism and acetaminophen? A. I mean, we can look A. Some of them -- I have to look ⁵ specifically in that regard, but using ⁵ specifically at Richey. I don't -- I don't ⁶ measures of depression or anxiety, I don't ⁶ think I drew any specific conclusions in ⁷ recall those specifically mentioned variables ⁷ regards to what Richey said about that. We ⁸ in the studies I reviewed. can look at it specifically, though. Q. Okay. You don't recall whether Okay. And those are not things ¹⁰ that Dr. Cabrera adjusted for in his or not Richey determined that a meta-analysis ¹¹ causation analysis when evaluating the 11 couldn't be done? ¹² studies, correct? A. Well, they did a meta-analysis. A. As I indicated, I'm unaware ¹³ I think you're asking me some very specifics ¹⁴ that depression or anxiety in and of about the meta-analysis that they did, and I think we should look at the study if you want 15 themselves can cause an adverse outcome in to discuss specifics about Richey. the offspring. 17 So accordingly, you didn't (Cabrera Exhibit 19 marked for ¹⁸ adjust for it, right? 18 identification.) A. I didn't know that they're a 19 QUESTIONS BY MR. MURDICA: ²⁰ risk factor in that regard. And as I Q. Okay. If I have time, we will. ²¹ mentioned, unless they're associated with a 21 I'm going to move to the next ²² one first. ²² risk exposure and then those should be ²³ adjusted for. We talked about meconium Okay. Dr. Cabrera, in your ²⁴ earlier, and you know there's a meconium

²⁵ review of human autism studies, did you note

²⁵ study with respect to ADHD and acetaminophen,

Page 370 Page 372 ¹ right, Doctor? ¹ have examined the potential mechanisms ² mediating the association of prenatal A. Yes, I do. 3 ³ acetaminophen exposure with neurodevelopment, And this is -- do you see it's ⁴ a key component for assessing the potential ⁴ in front of you marked as Exhibit 19? ⁵ for causation." Α. Yes, I do. 6 Did I read that correctly? And this is something that you ⁷ looked at and relied on in your paper, right? A. I -- you did, yes. Okay. And as of September 28, A. Yes, it is. 9 2020, do you disagree with that? And, in fact, this is something that you changed regarding this paper in your A. I would say there had been amended report, right, we talked about ¹¹ numerous mechanistic studies, but nothing ¹² earlier. 12 that had put all of the steps in regards to 13 neurodevelopmental toxicity together. I -- I did mention as far as ¹⁴ the period of exposure, that was consistent Q. Okay. By the way, do you know with meconium. any of the authors of this study? 16 A. I'm familiar with Andrea Okay. If you turn to page 5 of ¹⁷ Exhibit 19, I'm going to ask you a question ¹⁷ Baccarelli. ¹⁸ on the third paragraph -- a couple questions, 18 And you know Baccarelli is one 19 actually. of the plaintiffs' experts in this ²⁰ litigation, right? 20 So my first question is this, ²¹ the authors of this study write, "No single 21 A. I'm aware. ²² observational study is sufficient for causal 22 Okay. You don't disagree with ²³ Dr. Baccarelli's statements that I just read ²³ inference, and more observational studies 24 to you? ²⁴ using direct measurements of fetal ²⁵ acetaminophen exposure are needed." A. I do not. Page 373 Page 371 1 Do you see that sentence? Okay. Dr. Baccarelli and his 2 colleagues include a strengths and Yes, I do. A. ³ limitations section at the end of the Okay. Do you agree with that, as of the publication date of this article? article. A. I -- at the time there was My question for you is, on ⁶ only, I believe, the one cord blood study in page 11 where Dr. Baccarelli and his colleagues write, "Another possibility is ⁷ regard to -- actually, this is -- well, it ⁸ depends on the endpoint. confounding by unknown genetic, social and familial factors associated with So there was -- for ADHD -well, as far as measuring concentrations, we acetaminophen use." ¹¹ had the cord blood study that we already 11 Just -- sorry. 12 mentioned. Where exactly? Α. 13 And so we would prefer to have Q. Yeah. 14 ¹⁴ some sort of replication in that regards. Α. Last page? 15 Right. Yeah. About halfway down from Q. 16 16 These authors thought that more the top. 17 ¹⁷ observational studies were needed using A. Got it. direct measurements of fetal acetaminophen Do you see that sentence, exposure to reach causal inference, correct? "Another possibility is confounding by 20 unknown genetic, social and familial factors And that is what they say, yes. 21 associated with acetaminophen use"? And that was as of 2020, 22 correct, September 28, 2020? Yes, I do. 23 23 That is what is indicated, yes. Okay. And do you acknowledge Q. ²⁴ that that's a possibility? Okay. In going down a couple sentences, it says, "Third, no prior studies A. I acknowledge that it's a

Page 374 Page 376 ¹ possibility. I also knowledge that he I -- that's what Dr. Cabrera ² followed that up with, "This concern has been ² believes, correct? ³ recently addressed with negative control That's the reality we live in. A. ⁴ exposure analysis, maternal acetaminophen --Okay. Well, Dr. Cabrera, Q. ⁵ acetaminophen use before and after pregnancy you've seen today that I've shown you ⁶ and a partner's acetaminophen use were not ⁶ everybody in the world disagrees with you ⁷ associated with child ADHD in populations in ⁷ except other plaintiffs' experts? ⁸ which maternal acetaminophen use during MS. KING: Objection. Form. QUESTIONS BY MR. MURDICA: pregnancy increased the risk." 10 Q. So I appreciate your answer, O. Right. 11 ¹¹ but I'll ask Dr. Baccarelli about this in two And my question is, 12 weeks. ¹² Dr. Baccarelli and colleagues are 13 ¹³ acknowledging that unknown genetic, social MS. KING: Objection. Form. ¹⁴ and familial factors associated with ¹⁴ QUESTIONS BY MR. MURDICA: acetaminophen use are still a possibility, Q. Do you disagree, Dr. Cabrera, although he cites one study that he believes ¹⁶ with this sentence that Dr. Baccarelli and addresses it, correct? ¹⁷ colleagues wrote, "confounding by unmeasured 18 MS. KING: Objection to form. our unknown factors is always a possibility 19 ¹⁹ in relation to the effects observed in this THE WITNESS: To be clear, he 20 20 study"? actually cites three studies that 21 21 refute that, that being both the As I indicated, I -- my reading 22 ²² of that is that he's indicating he's -- or negative control exposure studies. 23 And then he follows that by ²³ referencing unmeasured confounding and 24 saying, "Furthermore, our study ²⁴ as a -- or unknown confounding, and so 25 ²⁵ that's -- it is a possibility. population has high genetic and Page 377 Page 375 1 sociodemographic homogeneity." You can't control every 2 So he's rejecting that ² variable in that regard, but they've also 3 ³ accounted for that as well. possibility also within reference 50 4 as well. They accounted for -- oh, ⁵ QUESTIONS BY MR. MURDICA: ⁵ really? They unaccounted for unmeasured and ⁶ unknown factors? Q. Okay. If you look at the first ⁷ sentence on this page, Dr. Cabrera, A. Well, you can't -- you can't account for the unknown. ⁸ Dr. Baccarelli and colleagues also write, ⁹ "Confounding by unmeasured or unknown risk Q. Okay. ¹⁰ factors is always a possibility." But the whole point is through 11 ¹¹ using their methods of analysis, they're, I Correct? 12 12 would say, mitigating that as much as He did write that. 13 possible. Q. Do you disagree with him on 14 14 that? Okay. But they didn't write 15 that because they don't believe it's a Well, I will make the general statement, there's always the potential for possibility, right? ¹⁷ residual confounding, and I believe that's 17 A. You don't -- you don't know ¹⁸ what he's referencing there. what you don't know that. 19 Q. Yeah. And that's what Okay. We can agree on that, O. ²⁰ Dr. Chung attributes the associations in some ²⁰ Dr. Cabrera. of the studies to, right? 21 All right. Let's go on to the 22 next one. Right, but it's -- based on the ²³ analysis that's been done, it's not All right. Dr. Cabrera, do you ²⁴ sufficient to account for the increased risk ²⁴ agree that 70 percent of adverse birth ²⁵ that's been reported in multiple studies. ²⁵ outcomes are of an unknown cause?

Page 378 Page 380 ¹ five years? MS. KING: Objection. Form. 2 THE WITNESS: Can you repeat A. Well, there -- there's still 3 ³ mouse models in that regard, but I think they the question? are informative into understanding the --**OUESTIONS BY MR. MURDICA:** Sure. particularly when we find rare mutations, and 6 we make animal models. Dr. Cabrera, do you believe ⁷ that 70 percent of adverse birth outcomes are I'm currently working on a of an unknown -- or from an unknown cause? mouse model with the rare gene mutation that's also associated with autism, and the I believe I have indicated that 10 animal model has been very informative. before. 11 11 You've testified to that before And that's changed in the last Q. under oath, correct? five years? 13 13 That's correct. Α. It's on a case-by-case basis. 14 14 (Cabrera Exhibit 20 marked for Q. Okay. And you stand by that? 15 I would say that over time 15 identification.) ¹⁶ we learn more, and over time, that percentage **QUESTIONS BY MR. MURDICA:** 17 ¹⁷ has gotten smaller. Okay. Last exhibit. We talked Do you agree that most issues a little bit about Ystrom. with the fetal-developing brain are for Do you remember that, as-yet unknown reasons? Dr. Cabrera? 21 21 MS. KING: Objection. Form. A. Yes. 22 22 THE WITNESS: We -- as -- over Mark that. O. 23 23 time, we've learned more about the You should have Exhibit 20 in 24 front of you now, Dr. Cabrera. particular genetic and environmental 25 A. Yes, I do. factors can impact those. Page 381 Page 379 1 1 And I would say it's -- it MS. KING: Can I have a copy? 2 would be fair that we're maybe MR. MURDICA: Yes. 3 approaching, and we can determine **QUESTIONS BY MR. MURDICA:** 4 risks, both environmental and genetic, Q. All right. Dr. Cabrera, do you for the majority of cases now. remember I asked you if impulsivity was **QUESTIONS BY MR. MURDICA:** associated with acetaminophen use during Okay. Understanding that when pregnancy? ⁸ you said it under oath five years ago, you Yes, I do. A. believed it was true then, right? Okay. If you look on page 2 in 10 A. Yes. the second column, will you agree with me 11 Q. Okay. When you said under oath that this group found that that -- previously 12 five years ago that animal -- knockout animal found that that was the case? models haven't been fruitful in converting to It's the second sentence in the ¹⁴ middle column on page 2. ¹⁴ human effect, did you mean that? 15 MS. KING: Objection. Form. A. I do see that, yes. 16 16 If you're going to quote from Okay. And assuming that's 17 his testimony, I would ask that you ¹⁷ true -- well, they obviously claim they found 18 18 show it to him. it, and they have a citation, right? 19 19 MR. MURDICA: Okay. A. They do. 20 QUESTIONS BY MR. MURDICA: Have you looked at that Q. 21 citation, Doctor? Do you agree with that or no? I think our knockout models Yeah. I believe they're ²³ referencing their previous work. ²³ have done fairly well in some regards for 24 animal models of human disease. Okay. Is that a potential sign ²⁵ of confounding that you need to count --Has that changed in the last

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Page 382
                                                                                                 Page 384
<sup>1</sup> account for?
                                                                Right?
            Impulsivity?
                                                      2
                                                                MS. KING: Objection. Form.
      A.
3
                                                      3
            A trait in the maternal
                                                                THE WITNESS: I will say
  population that uses acetaminophen that seems
                                                            there is consistency in that there's
  to be common.
                                                            an increased risk in each one of their
                                                      6
      A. I --
                                                            models, in regards to model 1, model 2
7
                                                      7
           MS. KING: Objection. Form.
                                                            and model 3, consistently show an
8
                                                      8
           THE WITNESS: As I previously
                                                            increased risk, although not
                                                      9
9
      indicated, I -- I'm unaware that
                                                            consistently statistically
10
                                                     10
      impulsivity as a trait can necessarily
                                                            significant.
11
      lead to adverse outcome.
                                                     11
                                                        QUESTIONS BY MR. MURDICA:
                                                     12
  QUESTIONS BY MR. MURDICA:
                                                                  Right.
13
                                                     13
      Q. Dr. Cabrera, impulsivity could
                                                                 In fact, in their adjusted
<sup>14</sup> be a symptom of an underlying condition
                                                       model, the majority of the outcomes are not
                                                        statistically significant, right?
  that could be associated with the two
  outcomes we are interested in, correct?
                                                            A. In their fully adjusted model,
17
                                                       as they have applied more adjustments, the
           MS. KING: Objection. Form.
18
           THE WITNESS: I would say that
                                                        odds ratios remain positive, but there
19
                                                       appears to be three that would not cross 1 in
      there's -- impulsivity could be --
20
      there could be overlap between ADHD
                                                       regards to their confidence intervals.
21
                                                                 Well, if you look at the far
      and impulsivity.
22
  QUESTIONS BY MR. MURDICA:
                                                       right, there's more than three, right? Only
23
            Okay. If you'd turn to
                                                     <sup>23</sup> one -- only three of them do have statistical
      Q.
<sup>24</sup> Table 1.
                                                       significance, right?
           This is the -- essentially the
                                                            A. Right. That's three of them do
                                                                                                 Page 385
                                            Page 383
<sup>1</sup> outcome table from their study, right?
                                                        not cross 1.
      Α.
            Yes, it is.
                                                                  Okay. Sorry.
                                                            0.
            Okay. And if you look at the
                                                                 The rest of them, Dr. Cabrera,
<sup>4</sup> far right, the last row, last column for
                                                        so seven or eight of them, are not
<sup>5</sup> mothers who were exposed to acetaminophen in
                                                        statistically significant, right?
<sup>6</sup> all three trimesters, the adjusted confidence
                                                                  Still an increase in risk, but
<sup>7</sup> interval is not statistically significant,
                                                        they're not statistically significant.
8 correct?
                                                                  Okay. And this is another one
      A. In the fully adjusted model,
                                                       of those studies where all this document is
<sup>10</sup> it's -- there's still an increased risk.
                                                        used at some particular time for some
<sup>11</sup> It's 1.27, and confidence interval goes from
                                                        particular duration in a trimester, not a
<sup>12</sup> 0.99 to 1.63. It would not be statistically
                                                       length of use or the actual portion of the
  significant based on --
                                                        trimester when the use was, correct?
14
            And if you look --
                                                                  Yes. So this -- their analysis
15
           -- crossing 1.
                                                       is largely based on duration of use. It
16
           Thank you, Dr. Cabrera.
                                                       doesn't necessarily tell you within a
           And if you look further up in
17
                                                       trimester when it was used.
<sup>18</sup> that column, you'll see there's quite a bit
                                                                  And that's unfortunate from a
                                                     19
<sup>19</sup> of inconsistency between uses in the
                                                        perspective of a teratologist like yourself,
<sup>20</sup> different trimesters.
                                                     20
                                                       right?
                                                     21
           For example, there's no
                                                                 MS. KING: Objection. Form.
                                                     22
<sup>22</sup> statistical significance for use in the
                                                                 THE WITNESS: The more
<sup>23</sup> second and third or first and third
                                                     23
                                                            information we have on the dose and
                                                     24
<sup>24</sup> trimester, but there is for the first and
                                                            the duration and the frequency of
```

25

exposure, the better.

²⁵ second trimesters.

		•	
	QUESTIONS BY MR. MURDICA:	1	known each other for years, haven't we?
	Q. Okay. And if we turn to the	2	
	³ very end of the study in conclusions, the	3	· · · · · · · · · · · · · · · · · · ·
- 1	⁴ last two sentences the last sentence the	4	-
	⁵ authors conclude, "We do not provide		have a lab called that's the Finnell/Cabrera
	6 definitive evidence for or against a causal		lab; is that right?
.	relation between maternal use of	7	A. The Finnell/Cabrera Birth
	8 acetaminophen and ADHD."	8	
	9 Do you see that?	9	Defects Research Laboratory.
1	•	10	Q. And what academic is that
1		11	associated with any academic institutions.
	Q. And based on the table we just		A. That's at Daylor Conlege of
	saw, you would agree, would you not,	13	Medicine.
	³ Dr. Cabrera, that this study in and of itself		Q. Okay. And prior to Baylor
- 1	doesn't provide evidence for or against a	15	College of Medicine, was it affiliated with
	5 causal relationship between acetaminophen and	16	another deddenne institution:
1	6 ADHD, correct?		A. Phol to that, we were at the
	A. All marvidual study typically	18	University of Texas at Austin
1	8 isn't going to provide enough data to		Q. Allu
1:	9 demonstrate a causal relation in that regard.	19	A and also part of the Den
2	WIK. MUKDICA. Okay.		Medical School.
2	Anything else:	21	Q. And are you known as a
2:	An right. I don't have	22	principal investigator?
2	anything cisc.	23	A. Yes, I am.
2.	Do you have any questions,	24	Q. What's a principal
2	RCOCCCa:	25	investigator?
	Oh, Sean's going to do it.	1	A. That means I lead National
	MR. WATTS: Sean, wake up.	2	Institutes of Health-funded research.
	MR. TRACEY: Yeah, I think I'm	3	Q. And what is the National
.	going to do it. Can we take, like, a	4	Institutes of Health?
	five-minute break?	5	A. Well, it's the governing body
	THE WITNESS: Please.	6	
	MR. TRACEY: Or do you want to	7	Q. And what is the primary purpose
	⁸ just roll now?	8	of the Finnell/Cabrera lab at Baylor College
	MR. WATTS: No, he wants to	9	of Medicine?
1		10	A. It's our our catch slogan is
1		11	prevention of preventable birth defects.
1:	MS. KING: Five minutes? Is it	12	Q. Okay. And you mentioned your
1	really five minutes?	13	boss a few times during the deposition.
1.	VIDEOGRAPHER: Off the record,	14	Is that Rick Finnell?
1	⁵ 5:36.	15	A. Yes, it is.
1	6 (Off the record at 5:36 p.m.)	16	Q. And what is Rick Finnell's job?
1	•	17	A. He's a clinical geneticist by
1	5:49 p.m., back on the record.	18	training, and currently the also a co-PI
1:	•	19	in the laboratory and a chair in the in
2		20	
2		21	Q. And how long have you worked
2		22	with Rick Finnell professionally?
2	- · · · · · · · · · · · · · · · · · · ·	23	A. I met Rick Finnell in 1995 as
2.	_	24	an undergraduate student when I was appointed
2	⁵ Sean Tracey, as you know. You and I have	25	to his lab by his wife as part of the honors

Page 390 Page 392 program at Texas A&M University. ¹ chemical-gene/protein interactions, ² chemical-disease and gene-disease Okay. What percentage of the ³ work at your lab deals in some form or ³ relationships. These data are integrated ⁴ with functional and pathway data to aid in ⁴ fashion with genetics? I would say the majority of the ⁵ the development of hypotheses about the ⁶ work we do has -- deals with genetics. ⁶ mechanisms underlying environmentally influenced diseases." But you're a teratologist, 8 right? Q. Let me stop you there for a A. That is correct. second. How does -- how does genetics, That section that says ¹¹ if it does, intersect with teratology? 11 "chemical-gene/protein interactions," is that what you do every day at your lab? So part of what we do is we ¹³ often start by looking at particular chemical 13 MR. MURDICA: Object to the 14 ¹⁴ exposures, and then we look for what's called form. gene environment interactions. And that is 15 THE WITNESS: Yes, that's what ¹⁶ particular changes in genetics that increase 16 I described just previously as gene 17 ¹⁷ the risk for an adverse outcome with an environment interactions. **QUESTIONS BY MR. TRACEY:** exposure. 19 19 Q. Okay. And then the next Q. And that's what you do in your sentence says, "We also have additional ²⁰ lab, that's your day job. ongoing projects involving manual curation of That's the bread and butter. 22 Okay. Do you remember during the exposome data and chemical-phenotype ²³ your -- Mr. Murdica's examination, he brought relationships to help identify pre-disease ²⁴ up this toxicogenomic database in the context biomarkers resulting from experimental {sic} ²⁵ of talking about some other databases. ²⁵ exposures." Page 393 Do you remember that? Do you know what that means? 2 Yes, I do. Yes, I do. A. A. And are we in a position where What does that mean? O. ⁴ we can pull up the database and put it on the So the exposome is the idea A. ⁵ that similar to a lot of the other OMIC data, ⁵ screen share? ⁶ in the environment we're exposed to a lot of I would be happy to. different compounds that can influence, Because what you -- what ⁸ Mr. Murdica had in front of you were printout what's referred here, as chemical and of screenshots, right? phenotype relationships. And the idea is 10 ¹⁰ that these models can be used to help drive A. That's correct. 11 11 research looking at potential biomarkers that Q. But this is the actual live ¹² database, right? ¹² may be indicative of particular exposures. 13 A. Yes, it is. Q. Okay. And then it says, the 14 14 next sentence says, "The initial release of And if we go over to home --¹⁵ oh, sorry. If you go over to CT -- yeah, go the CTD was November 12, 2004." to about us. There you go. And then under Support, it I want you to explain to the 17 ¹⁷ says, "This program is supported by funds ¹⁸ judge and the jury what is the CTD, the ¹⁸ from the National Institutes of Environmental comparative toxicogenomic's database? Health Sciences." 20 So as described in the Do you know what that is? ²¹ overview, that "CTD is a robust, publicly 21 Yes, I do. Α. 22 ²² available database that aims to advance Q. What is that? ²³ understanding about how environmental That's an institute under the ²⁴ exposures affect human health. It provides ²⁴ National Institutes of Health that

²⁵ manually curated information about

²⁵ specifically focuses on the effects of

Page 394 Page 396 ¹ environments on health. just the presentation that we see is the 2 Okay. So this database is phenotype. supported by the federal government. Q. Okay. Now, if we scroll back MR. MURDICA: Objection to the up, and we want to do what you did in your 5 form. report -- for example, if you go over and 6 you -- under Search, can you click on Search? THE WITNESS: The NIH and the 7 Well, this is what I would do. NIEHS are part of the federal 8 government. I would put chemicals --QUESTIONS BY MR. TRACEY: Q. Okay. 10 10 -- here, and I can type in --And the NIH is who you told us Α. 11 a few minutes ago gave you the grants. Q. But I want you to start with 12 ¹² Disease. They do fund my research, yes. 13 13 Yeah. Α. O. Oh, I can do diseases as well. 14 14 And then they go on to say, And I can --15 15 "We're also proud to be part of the NIEHS And type in "autism spectrum O. ¹⁶ Environmental Health Science Center at disorder," and I want you to tell us what ¹⁷ NC State, the Center for Human Health and the shows up and why it's important. ¹⁸ Environment." So it defines autism spectrum disorder as a continuum of associated And are you familiar with that ²⁰ organization at NC State? cognitive and neurobehavioral disorders, including, but not limited to, three A. I haven't been there, but core-defining features, impairments of apparently they have a program project there ²³ that's funding their center, similar to what ²³ socialization, impairments of verbal and ²⁴ nonverbal communication, and restricted and ²⁴ we have at Baylor. ²⁵ repetitive patterns of behavior, according to Q. Okay. And then just quickly Page 395 ¹ scroll down, they've got data categories, ¹ the DSM-5. ² because we're going to look at some of these. And then it's got a bunch of ³ Mr. Murdica had the printouts, and we're ³ tabs up there, and you can click on these and ⁴ going to look at the realtime search. get information; is that right? 5 They say the data categories A. That is correct. ⁶ they have are chemicals, diseases, genes, And so if you click on ⁷ "chemicals" -- let's do that, and tell us ⁷ phenotypes and chemical-gene/protein ⁸ interactions. what shows up. Is there any more? So the top hit is valproic acid 10 If we scroll down, is there followed by acetaminophen. 11 more? 11 Okay. And valproic acid, you and Mr. Murdica talked about, didn't you? Well, the last one would be anatomy they have here for their references. Yes, we have. 14 ¹⁴ It's also in the figure. Q. You -- I thought I heard you Okay. And you mentioned say, that's actually the model for causing 16 phenotypes, and I think y'all talked about it autism. ¹⁷ today, but nobody defined it. 17 A. That is correct. 18 18 What's a phenotype? And so on this Comparative 19 Toxicogenomics Database, when you type in the So the genotype-phenotype ²⁰ relationship would be best characterized by disease autism, does it mean that the number ²¹ Mendelian genetics where the phenotype of a one chemical interaction is valproic acid? ²² plant can be shorter or tall in regards to MR. MURDICA: Objection to ²³ the genes are the genotype that control 23 form. 24 ²⁴ whether the plant was short or tall, and THE WITNESS: Based on the 25 ²⁵ short or tall is the phenotype. So that's direct evidence of mechanistic

Page 398 interactions, valproic acid is the Folic acid is a provitamin in 2 ² the production of vitamin B9, which are a number one chemical. ³ family of folates, which are considered **QUESTIONS BY MR. TRACEY:** And is there a general -- is it ⁴ essential vitamins. generally accepted in the medical and Q. And does folic acid cause ⁶ scientific community, or the teratology autism? ⁷ community, that valproic acid causes autism A. It does not. Its indication spectrum disorder? there is that use of folic acid has been A. Yes. shown to reduce the risk of autism. 10 Q. Have you yourself proven that And Rick Finnell was one of the 11 in your lab? pioneers in that research, wasn't he? 12 We've tested that in animal 12 MR. MURDICA: Objection to A. 13 13 model, yes. form. 14 14 Okay. Number two on the list THE WITNESS: So we have done 15 is acetaminophen. some work in regards to the neural 16 That's correct. tube defect decreased risk and autism A. 17 17 Q. as well in regards to interaction with And we're going to come back to 18 that. 18 folate. 19 19 **QUESTIONS BY MR. TRACEY:** Number three is Bisphenol A. 20 ²⁰ What is that? And do you know, Dr. Cabrera, ²¹ whether it is recommended for all pregnant A. That's a monitor -- monomer mothers in the United States to take folic that used to be used in the production of acid to, in part, reduce the risk of autism? plastics. 24 Originally folic acid was used And was that removed from plastics? to fortify the food supply in order to reduce Page 399 1 the risk of neural tube defects. A. It was banned. 2 It was banned by who? More recently, it's been shown O. The federal government. to reduce the risk of autism as well. A. Okay. Is that known and Okay. So some of the things on ⁵ this list of the top ten, let's say, are generally understood to be associated with ⁶ associated with autism in a negative way in autism spectrum disorder? the sense that they cause it, and some are There were concerns that it could potentially increase risk for endocrine associated with it in a positive way in that disruption and autism spectrum disorder. they help reduce it; is that right? Q. Okay. 6 and 7, I'm just going MR. MURDICA: Object to form. ¹¹ to get you to highlight because you talked 11 Sean, if you're going to keep about them with Mr. Murdica in terms of 12 making misrepresentations and lead 13 confounding. like this, you just got to stop. 14 14 And that's air pollutants in You're testifying. 15 particular -- particulate matter, right? MR. TRACEY: Well, 16 16 That's correct. Dr. Cabrera --17 17 Q. And is there some evidence that MR. MURDICA: You got to stop, 18 air pollutants and particulate matter may Sean. 19 contribute to cause autism? **OUESTIONS BY MR. TRACEY:** 20 20 Q. Dr. Cabrera, tell us what it Yes, there is. ²¹ means when I see valproic acid, Okay. Folic acid is number 9. ²² acetaminophen, bisphenol A, et cetera, on ²² I know you know a lot about folic acid, ²³ this -- on this chart from the toxicogenomic 23 right? 24 ²⁴ databases, why is this important to you in Yes, I do. A.

²⁵ your opinion?

What is folic acid?

25

Page 402 Page 404 1 1 Yes. Well, there's --A. A. 2 And so I want you to show the MR. MURDICA: Objection to Q. 3 judge and the jury how to do this right so form. 4 they can understand your testimony. THE WITNESS: -- two parts. 5 One in that it's showing that there's, MR. MURDICA: Objection to 6 form. That's not a question. what we refer to, as direct evidence 7 MR. TRACEY: It is. for an interaction between valproic 8 **QUESTIONS BY MR. TRACEY:** acid and the disease. 9 And that's indicated here when Q. Can you show us how to do this 10 right, Dr. Cabrera, so that we can see how you highlight over this -- M is for 11 ¹¹ this database funded by the federal mechanistic interactions. 12 ¹² government shows that acetaminophen interacts And then also, it will identify 13 with genes and is associated with autism? genes that have been previously 14 14 associated or been shown to cause or Yes, I can. 15 15 And so as an example here, if increase the risk of autism that have 16 you click on the genes that are indicated in also been shown to be influenced by 17 ¹⁷ the network, those genes come up. They're exposure to either valproic acid or 18 part of a gene list where if you look at a acetaminophen. database, or actually even within this 19 **QUESTIONS BY MR. TRACEY:** 20 database, there are genes that have been And do you see -- can you go associated with or been shown to cause back to that? There you go. ²² autism. So that score, valproic acid and autism has a score of 264.59, right? 23 And if you click on an 24 ²⁴ individual gene, as an example, it will then That's correct. 25 25 show you the references that support those And there are 50 references Page 405 ¹ there to the right, and there's 311 genes interactions. ² there under the Inference Network, right? And so I'll use an example here ³ of clicking on COMT, one of the ones that we That is correct. ⁴ mentioned, or clicking on capicua, CIC, where Q. And there is no question in the ⁵ medical and scientific community that ⁵ they ask where it was in the database. If ⁶ you click on that, it then opens up the ⁶ valproic acid causes autism, is there? reference that indicates "acetaminophen MR. MURDICA: Object to the 8 affects the expression of capicua messenger form. 9 Sean, you can't testify. I RNA," and it provides you with a reference. 10 mean, that's not the way this works. And if you click on that **QUESTIONS BY MR. TRACEY:** ¹¹ reference, it will then provide you the study 12 ¹² that shows that acetaminophen was used in Can you answer my question, 13 Dr. Cabrera? ¹³ hepatotoxicity, as I indicated in my report, 14 ¹⁴ and shows the change in expression for A. There was no question. Okay. Now, when you were -capicua. when Mr. Murdica was showing you the 35 and And that can be done with any ¹⁷ the references and he clicked on that and he ¹⁷ of the genes in that -- in the gene family. did a little -- when we look at these So it could also be done with COMT as I'd studies, we don't see any mention of also mentioned, and you'll get changes in acetaminophen or Tylenol. ²⁰ COMT as well. And you can do that with any 21 Do you remember that? of the genes in the list. 22 Yes, I do. That's where the references ²³ are. 23 And you told him later on he 24 wasn't doing it right. Is it true, Doctor, and we can

Do you remember that?

²⁵ do some more if we need to, but if I -- you

Page 406 Page 408 **QUESTIONS BY MR. TRACEY:** ¹ click on any one of those genes --2 And that's what those are, Is that right? Q. 3 genes, right? That is correct. That's correct. A. It is a question. 5 Q. -- there is studies in this A. And there's two parts of this. 6 ⁶ federally supported database that link the So partially sorted by direct evidence and then by the inference score, ⁷ exposure to acetaminophen to either the ⁸ downregulation or the upregulation of the those are highest reported interactions. Okay. Let's do something. expression of these genes? Does anybody in the world that you know of MR. MURDICA: Objection to ¹¹ think that ibuprofen causes autism? 11 form. ¹² QUESTIONS BY MR. TRACEY: 12 Not that I'm aware. 13 13 Is that right? Let's do something just for ¹⁴ fun. Let's go back and type in "ibuprofen" 14 A. There are studies for each one and see if autism comes up. ¹⁵ of those genes. They'll be supported --¹⁶ there will be studies that support that You want to look at diseases? 17 ¹⁷ acetaminophen changes their expression. And Diseases, yeah. Q. ¹⁸ you can also filter that if you want to look 18 Do you see any autism there? 19 particularly at upregulation, or increase in I do not see that as a -- at ²⁰ expression, or downregulation, or decrease least as a top hit, and the inferences scores expression. are rather low. 22 22 O. Okay. And the score there for And then if you go to Q. acetaminophen and autism is 231, and the ²³ hypertension, that's number one for score for valproic acid is 264. ibuprofen? A. That is correct. A. That is correct. Page 407 Page 409 MR. MURDICA: Objection --Do you know whether or not ² ibuprofen is associated with hypertension? **QUESTIONS BY MR. TRACEY:** It is associated with Is that right? 4 ⁴ hypertension. It's one of the reasons why MR. MURDICA: Objection to 5 ⁵ it's contraindicated in late pregnancy. form. Okay. Okay. **QUESTIONS BY MR. TRACEY:** Now, how did you use this The inference score. 8 ⁸ database, if you did, to support your Is that right? 9 opinion? That is correct. A. 10 A. I used it to -- actually, and Ο. And in terms -- what is an ¹¹ largely in response to criticism that was "inference score"? 12 ¹² brought up by Dr. Chung in regards to having Α. So --13 ¹³ no gene or gene-drug interactions identified MR. MURDICA: Objection to 14 ¹⁴ in the literature. form. 15 Q. Okay. And this is the proof THE WITNESS: So as indicated, 16 16 that that's false. that's querying the database. It 17 17 MR. MURDICA: Objection to shows you the strength of this 18 18 form. interaction. 19 19 **QUESTIONS BY MR. TRACEY:** THE WITNESS: So --²⁰ QUESTIONS BY MR. TRACEY: And so number 1, the highest 21 inference score is valproic acid. Number 2 Is that right? is acetaminophen. As indicated in my report, this 23 ²³ data does report that there are overlapping MR. MURDICA: There's no 24 ²⁴ etiology in regards to genes between ADHD and question. Objection to form. 25

²⁵ ASD, and I reported that in my report

Page 410 Page 412 ¹ database. Can you go back to the main page again, just for a second, then we're Okay. And if the adverse going to leave this. ³ outcome pathway that's been published as Do you know -- do you know if ⁴ number 20 didn't exist, would you still have ⁵ the same opinions? ⁵ Johnson & Johnson has anything to do with A. Yes, and I would still go ⁶ this database? ⁷ through the same analysis, even in the A. I --8 absence of adverse outcome pathway number 20. MR. MURDICA: Objection. 9 What I want to do just for fun THE WITNESS: Not that I'm 10 10 is, can you search this pathway for the word aware. 11 "autism"? 11 **QUESTIONS BY MR. TRACEY:** 12 12 A. Yes, I can. Okay. Do you know if Johnson & 13 Hold on. Before you do that, Johnson gives any money to support this ¹⁴ before you hit -- oh, sorry. I was going to database? 15 read the actual title of the pathway. A. Not that I'm aware. 16 It's called "The binding of All right. Anything else we need to talk about on this database for now? ¹⁷ electrophilic chemicals to the SH thiol group 18 of proteins and/or to selenoproteins involved I think we've covered the 19 ¹⁹ in protection against oxidative stress during deficiencies that I've noticed earlier. 20 ²⁰ brain development leading to impairment of Okay. I want to flip and talk learning and memory." about this adverse outcome pathway for a Did I read that right? second. 23 23 That's correct. If somebody could bring up A. ²⁴ adverse outcome pathway 20 so we can put it And then over to the right are ²⁵ on the screen like we did this database. ²⁵ a bunch of authors, right? Page 413 By the way, you did -- you told A. That is correct. ² Mr. Murdica what you did was a weight of the O. Do you know if any of them work ³ evidence analysis, correct? for Johnson & Johnson? A. That is correct. I do not know that any of them And weight of the evidence Q. ⁵ work for Johnson & Johnson. ⁶ analysis means -- does it -- does it mean you Q. Okay. Go back and search for ⁷ "autism." I want to see whether it comes up weighed all the different lines of evidence? in this document. A. That is correct. And is there any one piece in So it indicates there's 15 your weight of the evidence analysis that if mentions of autism within the document. 11 it, you know, wasn't there, your opinion 11 Okay. Can we -- let's just would crumble to dust? ¹² look at a couple. I don't know if you can 13 ¹³ make that bigger. I'm blind, and I have some MR. MURDICA: Objection to 14 ¹⁴ my glasses on. form. 15 15 A. That good? THE WITNESS: Any one piece. 16 16 If there were deficiencies at multiple So there's a reference that 17 says, "The relationship between mercury and 17 steps, then you would be -- you would 18 ¹⁸ autism, a comprehensive review and have trouble drawing conclusions. 19 ¹⁹ discussion." And that's referenced in this **QUESTIONS BY MR. TRACEY:** 20 paper? Well, let me ask it this way. 21 If the toxicogenomic database A. That is correct. ²² didn't exist, would you still have the same 22 And then down below, it's got ²³ "Landa, diagnosis of autism spectrum ²³ opinion? disorders in the first three years of life." I could still draw -- I could ²⁵ still make the opinions in the absence of the That's another one?

Page 414 A. Yes. disorders such as autism and schizophrenia.' Let's go to the next one. "The 0. Do you agree with that? ³ role of epigenetic change in autism spectrum I -- yes, that has been A. ⁴ disorders," and that's in the Frontiers of reported. ⁵ Neurology, there at the top page 23? "The Q. Okay. Same -- next paragraph, ⁶ role of epigenetic change in autism ⁶ they mention autism again saying, "Genes ⁷ spectrum" -- oh. ⁷ involved in gluta -- glutamatergic pathways affecting receptor signalling metabolism and A. I -- yes. 9 transport were enriched in genetic variants It's a stream site, isn't it? O. ¹⁰ Yeah. associated with autism spectrum disorder." 11 11 Is that right? A. Yes, it is. Okay. Do you know whether or 12 12 Yes, it is. A. 13 not epigenetic change has been associated What does that mean? O. 14 with autism? A. Simply that if you looked at 15 those genes that have been associated with MR. MURDICA: Objection to 16 autism spectrum disorder, and that is, genes 17 that have been known to modify or increase THE WITNESS: Yes, I do know it 18 risk for autism, that they also overlap has been associated. ¹⁹ functionally and mechanistically with 19 **QUESTIONS BY MR. TRACEY:** 20 glutaminergic pathways. Okay. In your lab, do you Just click on another one. spend a great deal of your time studying and researching epigenetic changes? Just go to one more through there. 23 MR. MURDICA: Objection to There we got another paper. 24 ²⁴ That may be the same guy. form. 25 A. Yeah. I think this is the THE WITNESS: Yes, we do. We 1 ¹ reference that they were referencing in those recently published an epigenetic study 2 looking at the interaction of folate ² studies. or folic acid specifically on 3 Yeah. Okay. Click one more in Q. 4 ⁴ that. epigenetic changes in the animal model 5 or mice. "Autism and intellectual ⁶ QUESTIONS BY MR. TRACEY: ⁶ disability: Two sides of the same coin." Okay. Keep clicking. Let's That's referenced in this paper, isn't it? ⁸ see what else comes up in this adverse A. Yes, it is. outcome pathway on autism. Now, the name of this adverse Okay. "The putative role of outcome pathway though isn't autism; they're ¹¹ environmental mercury and the pathogenesis talking about memory and learning, right? and pathophysiology of autism spectrum 12 That is correct. 13 disorders and subtypes." Do you know why autism is ¹⁴ referenced so many times in this adverse 14 What's next? There we go. 15 Is this in the body of the AOP outcome pathway that's been published and 16 publicly available? here? 17 17 MR. MURDICA: Object. Object MR. MURDICA: Objection to 18 18 to the form. form. 19 19 **QUESTIONS BY MR. TRACEY:** THE WITNESS: Because there's 20 20 Can we tell? overlap in the outcome with particular 21 21 exposures and their impact on This is page 47 of the AOP. A. And they mention there in the 22 neurodevelopment that can lead to both ²³ middle, "Indeed, disruption of glutamate, 23 intellectual disability, autism and ²⁴ signalling is thought to be part of the 24 other neurodevelopmental disorders,

²⁵ etiology underlying some neurodevelopmental

including ADHD.

Page 418 ¹ QUESTIONS BY MR. TRACEY: ¹ scientific journal, then it's -- it will be ² sent out by multiple reviewers, and that's And do you use adverse outcome ³ pathways in your -- in your -- during your -part of what we refer to as the peer review ⁴ in your day job? process. We find reviewers for a paper I find them helpful, and the ⁶ answer is yes. I find them helpful for ⁶ based on common publications of those ⁷ reviewers with the topic of the publication, ⁷ identifying where there's deficiencies in research so that we can develop hypotheses and then they review it and criticize it or and obtain funding to test those hypotheses. find deficiencies in it. And do you teach that to And that gets returned back to 11 ¹¹ the author to correct or to respond to those students? 12 ¹² criticisms in order to have the paper meet an I do teach it to my students, 13 ¹³ expected scientific standard. yes. 14 Q. Okay. The toxicogenomic Okay. And have you yourself ¹⁵ database that we were on a few minutes ago ¹⁵ been a peer reviewer? ¹⁶ supported by the federal government, do you A. I've acted as both peer ¹⁷ use that database in your day job? ¹⁷ reviewer and editor for various journals. Occasionally. When I have to Q. And on the topic of birth 19 look up data on a -- on a chemical that I'm defects or adverse birth outcomes? ²⁰ researching, I'll often start with the 20 Yes. I've been guest editor ²¹ for Birth Defects Research, and I'm currently ²¹ database searches as it's normal to start ²² with what's known in the databases, both the acting as a guest editor for Reproductive ²³ chemistry databases and the genetics and ²³ Toxicology. ²⁴ genomics databases. Q. And so you -- you've done ²⁵ what -- you've been the peer reviewer where Q. Do you remember when ¹ you looked at somebody else's scientific ¹ Mr. Murdica was clicking on 35 and bringing ² up those papers and said none of them said ² work; you made edits; you made comments; you ³ acetaminophen? ³ asked questions, right? A. I still do that as well, yes. Do you remember that? And you yourself -- you've had A. Yes. I do. ⁶ your homework graded when you've submitted it How come he couldn't find ⁷ to peer review by other experts in the field, acetaminophen? Well, that study that's -- we 8 haven't you? ⁹ were -- that I would reference in regard to A. Yes, I have. ¹⁰ Santos was a methodology. It's describing And all that is part of the ¹¹ the method I was using. ¹¹ scientific process that is so important to worldwide scientific knowledge, isn't it? It wasn't describing the genetic analysis that I did, which you have 13 MR. MURDICA: Objection to 14 ¹⁴ to click on the genes in order to look at the form. 15 genetic analysis. You're doing it again, Sean. 16 16 See if you can ask a non-leading Q. So he was just in the wrong 17 place? 17 question. You're obligated to. 18 18 A. That is correct. MR. TRACEY: Okay. I'm trying 19 19 to move us out of here quickly, but, Okay. Do you -- Dr. Cabrera, you're familiar with the peer review process? 20 Robert --21 21 Yes, I am. MR. MURDICA: Doesn't --A. 22 22 Q. What is the peer review doesn't feel that way. 23 ²³ QUESTIONS BY MR. TRACEY: process? 24 If you want to publish a paper Tell us why the peer review

25 that is going to be in a reputable,

process is important.

	5		
	Page 422 1 A It's important that the	1	REDIRECT EXAMINATION
	A. It's important that the research meets a standard and that people	2	REDIRECT EXAMINATION
	3 that are proficient in the field can	3	
	⁴ understand it and potentially reproduce it.	4	the answers that you gave me under oath so
	In order for to provide that	5	far today?
	⁶ information, it needs to be reviewed by	6	•
	others to meet that standard.	7	
	⁸ Q. Okay. And you participate and	8	asking you questions, several of them, about
	⁹ support the peer review process; is that	9	Rick Finnell and Rick Finnell's
	¹⁰ right?	10	
	¹¹ A. Yes, I do.	11	Finnell.
	Q. Mr. Murdica showed you a	12	
	document, I think it might be Exhibit 17, but	13	· · · · · · · · · · · · · · · · · · ·
	was that a peer review of AOP 20?	14	Q. You also know, Dr. Cabrera,
	¹⁵ A. Yes, that has been	15	-
	¹⁶ peer-reviewed as well.	16	from Sean Tracey and other plaintiffs'
	Q. Okay. Anything in that peer		lawyers involved in this litigation, right?
	18 review that you read on your break that	18	MS. KING: Objection, form.
	¹⁹ alters one word of your opinion?	19	MR. TRACEY: Object to the
	MR. MURDICA: Objection to	20	form.
	form.	21	THE WITNESS: I don't I
	THE WITNESS: No, there's not.	22	don't know now much money ne's
	²³ QUESTIONS BY MR. TRACEY:	23	receiveu.
	Q. Okay. That looked like a	24	QUESTIONS DT MIK. MUKDICA.
-	²⁵ typical peer review process?	25	Q. You know that Mr. Tracey has
	A. Well, they some of them can	1	hired him for other birth defect litigation,
	² be pretty intense, so I would say it was	2	right?
	³ it was a maybe an average yeah, an	3	MR. TRACEY: Object to the
	⁴ average peer review process.	4	form.
	⁵ Q. Okay. All right. All of your	5	THE WITNESS: I I'm aware.
	⁶ opinions that you've given and gave in your	6	QUESTIONS BY MR. MURDICA:
	⁷ report are based on reasonable scientific	7	Q. You're aware. You've testified
	8 certainty?	8	under outil about it before, fight.
	⁹ A. Yes. All the opinions I've	9	A. IIII awaic.
	given have been provided within a reasonable	10	Q. Okay. That it goes, you got
	degree of scientific certainty.	11	into this business of taking money from
	Q. Tell me what percentage of your	12	plaintiffs' lawyers from Dr. Finnell who
	adult life you've been engaged in trying to	13	originally was the one taking money from
- 1	find out the cause of and ways to prevent	14	planians lawyers, right.
	15 birth defects.	15	MS. KING. Objection, Polin.
	A. Actually, all of my adult life	16	QUESTIONS DT MIK. MUKDICA.
- 1	¹⁷ I've been working either in genetics or birth	17	Q. The got you into it:
	18 defects research. 19 O Vour entire professional life?		A. 10 be clear, Richard Phillen
	Q. Tour churc professional me:	20	has worked with both the defense and
	A. Tean, starting as an	21	plaintiffs in the past and has been
	and graduit and community on increased.	22	occurse i recuir ne s occir returned in the
	MIK. TRACET. And Okay. An	23	past also by defense.
	right. Dr. Cabrera, I'll save the rest for later. Thank you.	24	i articularly i tillik lie was
	rest for fater. Thank you.		actually on a panel for joinison & joinison in

25 the past.

I'll pass the witness.

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Page 426
                                                          <sup>1</sup> question had come up about where was CIC in
       Q. You testified under oath before
                                                          <sup>2</sup> the database, and so that was what I clicked
 <sup>2</sup> that he did one case for one defendant for a
 <sup>3</sup> short amount of time.
                                                            on to show you.
                                                                      And it gave the Beyer article,
            Do you remember testifying to
 <sup>5</sup> that in 2018?
                                                          <sup>5</sup> which we previously marked as an exhibit,
       A. As I just indicated.
                                                          6 right?
             Okay. And you know that
                                                          7
                                                                A.
                                                                       That's correct.
 <sup>8</sup> Dr. Finnell has worked for plaintiffs'
                                                                Q.
                                                                       And you weren't able to show
 <sup>9</sup> lawyers on birth defect cases. By and large
                                                            where CIC was in the article, correct?
<sup>10</sup> that's been his expert involvement in
                                                                A. I told you it was in the data.
                                                         11
<sup>11</sup> litigation, right?
                                                                Q.
                                                                       Right.
12
                                                         12
       A.
             He has done that, yes.
                                                                     And we didn't see that on what
13
             And that's how you got
                                                            you just brought up on the -- on the computer
                                                            screen, correct?
<sup>14</sup> introduced to this, right?
                                                         15
       A.
             We used to have a company
                                                                 A.
                                                                      We didn't -- we didn't dig
<sup>16</sup> together.
                                                            that deep into the data.
17
                                                         17
             Okay. When you brought up the
                                                                      That didn't fill in the gap of
       Q.
<sup>18</sup> database onto the computer screen, one of the
                                                            what we were missing, right?
<sup>19</sup> things Mr. Tracey had you read was the
                                                                     MS. KING: Objection. Form.
<sup>20</sup> base -- the background on the database, and
                                                         20
                                                                     THE WITNESS: We didn't dig
<sup>21</sup> it said -- well, you read into the record
                                                         21
                                                                 that deep into the data.
<sup>22</sup> that it was intended to aid with the
                                                            QUESTIONS BY MR. MURDICA:
<sup>23</sup> development of hypotheses.
                                                         23
                                                                 Q. Okay. If I leave a blank in
24
                                                         <sup>24</sup> the transcript right here, will you fill in
            Correct?
25
                                                         <sup>25</sup> when you -- when you get -- review and sign
             That's correct.
                                               Page 427
             And that's what you used it
                                                            the transcript, will you fill in where that
 <sup>2</sup> for, right?
                                                            mention is actually found in Beyer?
       A. Initially, as I just told you,
                                                                 A. I can --
                                                          4
 <sup>4</sup> I looked at that database in order to see if
                                                                     MS. KING: Objection. Form.
 <sup>5</sup> there -- if and how many genes there were
                                                                     THE WITNESS: I can -- I can
 <sup>6</sup> that were common to the etiology of ADHD and
                                                                look into it.
                                                            QUESTIONS BY MR. MURDICA:
 <sup>7</sup> ASD.
       Q.
                                                                 Q. Thank you, Doctor.
            Right.
            And what the database says --
                                                                     If, when we get the transcript,
<sup>10</sup> there's a disclaimer that I'm sure you've
                                                            the blank that we're going to put is not
<sup>11</sup> seen that says, this should not be used to
                                                         <sup>11</sup> filled in, can we agree that it doesn't
<sup>12</sup> diagnose any condition or disease, right?
                                                         <sup>12</sup> exist, and it's not actually in that
13
            That is correct. It's not for
                                                         <sup>13</sup> citation?
                                                         14
<sup>14</sup> diagnosis.
                                                                     MS. KING: Objection. Form.
15
                                                         15
            Right.
                                                                     THE WITNESS: We could agree
                                                         16
            And the fact that there's a
                                                                that I didn't find it.
<sup>17</sup> number of genes allegedly connected to a
                                                            QUESTIONS BY MR. MURDICA:
  particular compound and an outcome doesn't
                                                         18
                                                                      Okay. Fair enough.
  mean that it's causative, correct?
                                                         19
                                                                     Mr. Tracey had you reading
19
                                                         <sup>20</sup> from -- oh, by the way, if you were to click
             That in and of itself is not
                                                            on more of those genes, we would end up with
<sup>21</sup> enough evidence to conclude causality.
       Q. And the example he showed you,
                                                         <sup>22</sup> the other article marked that was responsible
<sup>23</sup> you clicked on CIC. That was the first gene
                                                         <sup>23</sup> for 217 of those 273, right, the one I showed
  you clicked on, right?
                                                            you earlier?
       A. As indicated earlier, I -- the
                                                                      Potentially.
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Page 430 Page 432 Q. Right. Q. Right. 2 And that -- we never found --And for identifying potential ³ in two of the articles I showed you, we never gene compound outcome interactions, right? ⁴ found mention of the genes of the two that we It's used that -- for that as ⁵ actually looked at, right? well. 6 In that particular article, we O. Yeah. did not see them. It doesn't prove causation in Right. any given circumstance by itself, correct? And that's responsible for the By itself, currently, it does 10 ¹⁰ majority of the alleged gene interactions not --¹¹ that Mr. Tracey had you click on, right? 11 Q. Okay. 12 I can certainly look into that. A. -- demonstrate causation. 13 Okay. And if we were to open Then Mr. Tracey showed you O. ¹⁴ others, I'm not going to make you do it right AOP 20, and he had you read the instances 15 now, but you tell me if you know this, I just where the word "autism" appeared. ¹⁶ clicked on, on my own computer, FMO1, which Do you remember that? 17 ¹⁷ was one of those genes, and it lists a couple A. Yes, I do. ¹⁸ different references. And one says that Okay. And one of them he had acetaminophen upregulates FM01 and then right you read about, that autism shares pathways ²⁰ there, there is another reference that says with glute -- shares -- has commonality with acetaminophen downregulates FMO1. glutamatergic pathways. You've seen that, right? Do you remember that? There are examples where the 23 Yes, I do. A. ²⁴ expression can change, depending on both Okay. And that has nothing do ²⁵ which tissues they're testing, which cell with this case. That's GABA, right? Page 433 1 ¹ lines they're testing or the dosages they're That is GABA. Yeah. And GABA is not one of ² testing. You find differences in response. Q. ³ the mechanisms of action you've postulated in Yeah. There's -- you agreed ⁴ any way to do with acetaminophen and the two ⁴ with me earlier that the criteria for outcomes here, right? ⁵ including a gene in that is just that some ⁶ article somewhere mentions it somehow as I did not discuss GABA. ⁷ associated in some way, right? There's a --And when you looked carefully ⁸ you could look at the listing of what words ⁸ at what we're calling the peer review part of ⁹ they pick up on to determine whether to ⁹ AOP 20, you saw clearly that the reviewers ¹⁰ include it, right? ¹⁰ said, "Unless the authors want to change the ¹¹ ad" -- "the adverse outcome to autism, then It is a text-based query, and ¹² you can then sort through that text base. So 12 they should delete it. The authors must ¹³ if you want to look at just the genes that ¹³ delete the sentence in the overall assessment ¹⁴ are downregulated, you can find that, or just ¹⁴ domain of applicability section where they ¹⁵ the genes that are upregulated. You can also refer to autism. This is not an AOP for ¹⁶ look at protein interactions if you want to autism, and if that's the intention, it must ¹⁷ be changed." ¹⁷ look at mechanistic interactions as well. 18 It's someone's attempt to put You saw that when you were all the data they can find together in one reviewing it, right? place and let the viewer decide what to do 20 MS. KING: Objection. Form. ²¹ with it for hypothesis generation, correct? 21 THE WITNESS: I read that. Well, it's also the state of QUESTIONS BY MR. MURDICA: 23 ²³ the art right now for mining existing Q. Yeah. You don't agree with ²⁴ scientific literature for information that ²⁴ Mr. Tracey that this is about autism in any

²⁵ can be helpful for regulatory purposes.

²⁵ way, shape or form, correct?

Page 434 Page 436 1 Yes, they do. MS. KING: Objection. Form. A. 2 Do you know whether or not THE WITNESS: So to be clear, Q. 3 ³ Baylor College of Medicine, because they the AOP still has language in regard to interaction with autism and ⁴ receive money from Johnson & Johnson, forbid Rick Finnell from testifying in this case? reference with autism as an endpoint. QUESTIONS BY MR. MURDICA: That is correct. 7 What do you think of that? Q. It has -- it has the mentions O. 8 ⁸ like what you looked at with Mr. Tracey, MR. MURDICA: Objection to 9 right? form. 10 10 Α. In addition to what I've THE WITNESS: Well, it's a ¹¹ referenced in my report. 11 little bit upsetting. A little bit 12 12 disturbing. Right. 13 13 **QUESTIONS BY MR. TRACEY:** What it -- what it doesn't say 14 ¹⁴ is that autism is an outcome as part of that That someone can throw their AOP. And it's very clear, is it not, from money around and stop scientists from ¹⁶ the review, that that was not permitted to be testifying? 17 17 part of it? MR. MURDICA: Hang on. 18 18 MS. KING: Objection. Form. Objection to form. 19 19 THE WITNESS: That's correct. THE WITNESS: But -- I don't 20 20 MR. MURDICA: Sean, you said know about permission, but they ask 21 21 that it's either -- the AOP itself be that Baylor -- you're testifying, 22 22 changed to autism-specific AOP, or Sean, but you're testifying that 23 23 Baylor is preventing Finnell, correct? that it be removed, and they chose to 24 24 MR. TRACEY: That's right. remove it. 25 25 Because they receive money from Page 437 Page 435 QUESTIONS BY MR. MURDICA: Johnson & Johnson, they are preventing 2 ² him from testifying in this case. Q. Right. MR. MURDICA: Yeah. Okay. You And the author acknowledged, in ⁴ what we read before, that they couldn't don't -- you don't know that. That is ⁵ change it to autism because there wasn't improper. That is definitely not -enough data to support it, correct? MR. TRACEY: I do know it, MS. KING: Objection. Form. because I've seen the letter. 8 THE WITNESS: That was, in MR. MURDICA: Well, you're not 9 part, what we read earlier. under oath, and you're not giving 10 MR. MURDICA: Okay. I don't witness testimony, so you need to 11 stop. 11 have any other questions. 12 **RECROSS-EXAMINATION** MR. TRACEY: Well, I know. 13 ¹³ That's why I'm asking Robert **QUESTIONS BY MR. TRACEY:** 14 Cabrera ---Q. Dr. Cabrera, Mr. Murdica likes 15 15 to talk a lot about money and plaintiffs' MR. MURDICA: You told him. 16 16 lawyers. MR. TRACEY: -- because he 17 knows it, and I need to get the Have you noticed that? 18 I've heard it a few times. testimony from him. 19 Yeah. I want to talk about MR. MURDICA: I think you forgot how to ask a question, money and Johnson & Johnson for a minute. 21 Mr. Tracey. But you need to stop. Okay? 22 MR. TRACEY: I've forgot --A. Okay. ²³ I've forgotten so much, Jim, I don't Do you know whether or not ²⁴ Baylor College of Medicine receives money know where to begin.

²⁵ from Johnson & Johnson?

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<sup>1</sup> QUESTIONS BY MR. TRACEY:
                                                          FURTHER REDIRECT EXAMINATION
      Q. But let me ask you this.
                                                    <sup>2</sup> QUESTIONS BY MR. MURDICA:
3
          Dr. Cabrera, you know, sir,
                                                         Q. Dr. Cabrera, you testified
<sup>4</sup> don't you, that Baylor College of Medicine
                                                    <sup>4</sup> earlier that Baylor doesn't even know the
<sup>5</sup> refused to allow Rick Finnell to testify in
                                                    <sup>5</sup> crazy opinions you're espousing here, right?
<sup>6</sup> this case because they receive money from
                                                    <sup>6</sup> You never told them?
<sup>7</sup> Johnson & Johnson?
                                                             MS. KING: Objection. Form.
          MR. MURDICA: Objection to the
                                                     QUESTIONS BY MR. MURDICA:
9
      form. I mean, that is literally --
                                                         Q. Do they know you're out here
10
          MR. TRACEY: Do you --
                                                     creating a health hazard?
11
                                                   11
          MR. MURDICA: Can you ask a
                                                             MS. KING: Objection. Form.
12
                                                     QUESTIONS BY MR. MURDICA:
      non-leading question?
                                                   13
13
  QUESTIONS BY MR. TRACEY:
                                                         Q. Dr. Cabrera, does Baylor know
14
      Q. Let me flip it around.
                                                     what you're doing?
15
                                                   15
          Do you know whether or not
                                                             MS. KING: Objection. Form.
                                                   16
<sup>16</sup> Baylor College of Medicine forbid Rick
                                                             MR. TRACEY: Don't answer those
<sup>17</sup> Finnell from testifying in this case because
                                                   17
                                                         questions. Those are abusive and
  they received money from Johnson & Johnson?
                                                         insulting and unbecoming.
19
          MR. MURDICA: Objection to
                                                      QUESTIONS BY MR. MURDICA:
20
                                                   20
                                                         Q. Dr. Cabrera, does Baylor know
      form.
                                                   <sup>21</sup> what you're doing today and the opinions that
21
          THE WITNESS: That is correct.
                                                      vou're offering?
  QUESTIONS BY MR. TRACEY:
23
                                                   23
      Q.
                                                              As I already indicated, I'm on
           Okay.
                                                     vacation today.
           That was the reason they gave
<sup>25</sup> him that he could not testify.
                                                         Q. Right.
                                          Page 439
                                                                                             Page 441
            That was the reason they gave
                                                              Did you ask Baylor anything
<sup>2</sup> him.
                                                    <sup>2</sup> about Dr. Finnell and whether or not he could
3
                                                    <sup>3</sup> testify in this litigation?
           MR. MURDICA: Objection to
4
                                                         A. I didn't ask Baylor about
      form.
5
                                                    <sup>5</sup> what -- whether Dr. Finnell could, but he did
           MR. TRACEY: Sorry, I spoke
6
                                                    <sup>6</sup> disclose that information to me. And he told
      over you.
  QUESTIONS BY MR. TRACEY:
                                                     me that Baylor said that he would not be
                                                     allowed to testify.
           I just want to make sure.
9
                                                              So Dr. Finnell told you
           Is that what you said?
10
                                                      something that he allegedly heard from
           That is the reason they gave
                                                     Baylor, correct?
  him; that he was -- that he would not be
                                                   12
                                                              MS. KING: Object to form.
  allowed to testify.
                                                   13
13
                                                              THE WITNESS: It's not that he
           MR. MURDICA: Objection to
                                                   14
14
                                                         allegedly heard. He had communication
      form.
                                                   15
                                                         in that regard.
  QUESTIONS BY MR. TRACEY:
16
                                                   16
                                                     QUESTIONS BY MR. MURDICA:
      Q. Okay. Do you know whether he
  agrees with you?
                                                         Q. But you did not. You didn't
18
                                                   <sup>18</sup> hear it, did you? Did you see a
           MR. MURDICA: Objection to
19
      form. This is not -- if you want
                                                     communication?
20
                                                   20
      Dr. Finnell, get Dr. Finnell. This is
                                                              I have -- I have not seen a
21
      not about Dr. Finnell.
                                                     communication.
22
           THE WITNESS: He does agree
                                                         Q. Okay. Did Dr. Finnell ask
                                                   <sup>23</sup> Baylor before deciding whether or not he
23
      with me.
24
                                                   <sup>24</sup> could do that here?
           MR. TRACEY: All right. Thank
25
      you, Dr. Cabrera. Pass the witness.
                                                              He asked before he could
```

_	
Page 442	MR. TRACEY: Thanks,
² Q. He asked, but you didn't,	² Dr. Cabrera.
³ right?	THE WITNESS: Thank you.
⁴ A. I my conflict of interest is	l .
A. 1 my commet of merest is	VIDEOGRAPHER: Okay. Off the
⁵ through my company. He was going to testify	16C01u. 0.36.
⁶ as an individual employee of Baylor.	⁶ (Deposition concluded at 6:38 p.m.)
Q. So if he had a company, it	
⁸ would be different?	8
⁹ A. As it used to be when we were	9
¹⁰ part of the same company, we consulted under	10
¹¹ our company.	11
Q. Okay. So you were just asked	12
¹³ questions about something that you heard	13
third-hand from Dr. Finnell that he allegedly	14
	15
15 asked Baylor about but you didn't, right? MS KING: Objection Form	16
MS. KING. Objection. Polin.	
THE WITNESS: I heard firsthand	17
from Dr. Finnell in that regard.	18
¹⁹ QUESTIONS BY MR. MURDICA:	19
²⁰ Q. Right.	20
About something he allegedly	21
²² heard from Baylor itself, right?	22
A. About his communication with	23
²⁴ Baylor.	24
	25
O. Okay.	
Page 443	Page 445
¹ A. He told me that it wasn't that	1 CERTIFICATE
¹ A. He told me that it wasn't that ² I went out and asked him. He told me that	CERTIFICATE 1 CERTIFICATE 2 I, CARRIE A. CAMPBELL, Registered Diplomate Reporter Certified Realtime
¹ A. He told me that it wasn't that ² I went out and asked him. He told me that ³ about what was going on.	1 CERTIFICATE
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